Technical Documentation – Part 6-1-1:

Clinical Evaluation

of the Medical Device

Disposable inserts “Dailee Discreet Premium“

In accordance to MEDDEV 2.7/1 rev. 4 and Regulation (EU) 2017/745

Manufacturer	
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Content

1 Basic Information and Scope

Name of the document: Technical Documentation – Part 6-1-1: Clinical Evaluation of the Medical Device Disposable inserts “Dailee Discreet Premium“.

Purpose of the document: Purpose of this document is to carry out the report the clinical evaluation of the medical device Disposable inserts “Dailee Discreet Premium“. Document is issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter in technical documentation referred to as “MDR”), and MEDDEV 2.7/1 rev. 4 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under 93/42/EEC and 90/385/EEC.

Clinical evaluation definition: Clinical evaluation is a process designed to critically evaluate clinical data and demonstrate the safety and efficacy of the medical device, when used in accordance to intended use and standard conditions of their use.

Clinical evaluation must be precise and objective and must account both favourable and unfavourable data. Its depth and scope must be adequate and appropriate in relation to characteristics, classification, intended purpose and risks of the medical device as well as all the declarations of the manufacturer.

A clinical evaluation shall follow a defined and methodologically sound procedure based on the following:

(a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:

- it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 3 of Annex XIV, and
- the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under Articles 62 to 80, any acts adopted pursuant to Article 81, and Annex XV; and

(c) a consideration of currently available alternative treatment options for that purpose, if any.

Evaluator: Clinical evaluation conducts evaluator(s), who possess knowledge of the following:

(a) research methodology (including clinical investigation design and biostatistics);

(b) information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline);

(c) regulatory requirements; and

(d) medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review and clinical data appraisal).

2 Process of Clinical Evaluation

Clinical evaluation is based on detailed analysis of clinical data, which are relevant to intended use of the medical device. Clinical data might be available from both, phase before and after market release. Clinical data contain information on safety and/or efficacy of the medical device.

The clinical evaluation shall be planned, performed and documented in accordance with Article 61 and Annex XIV to MDR.

The clinical evaluation process is divided into several parts (Figure 1).

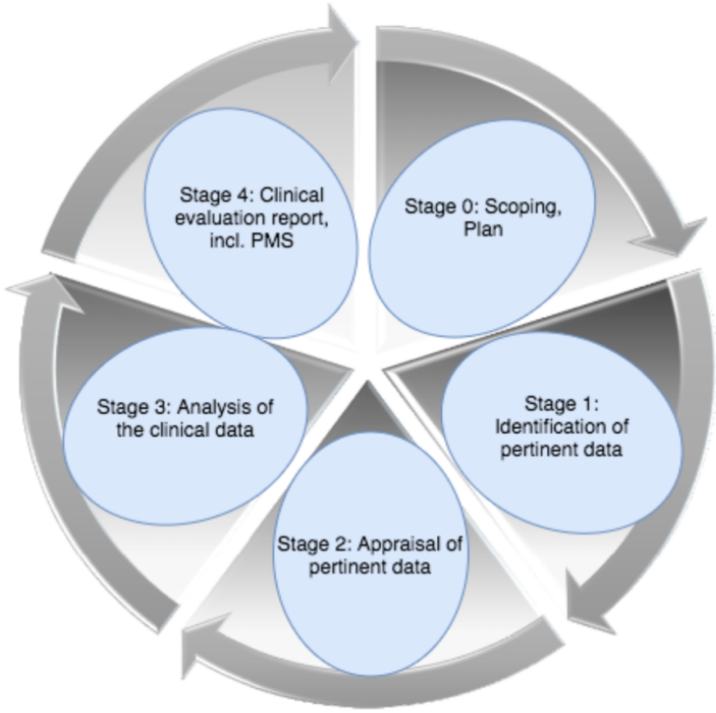


Figure 1: Clinical evaluation procedure by MEDDEV 2.7/1 rev. 4.

Stage 0: Scoping, Plan: Scope preparation and planning of clinical evaluation. This stage serves as a basis for following clinical evaluation stages and is based on essential requirements, clinical perspective, characteristics and origin of the medical device.

Stage 1: Identification of pertinent data: Clinical data might be sourced from:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.

Stage 2: Appraisal of pertinent data: Data appraisal by their reliability, relevancy and weight. In case of data sourced from scientific literature, the weight of data is based on the level of evidence of source study. Types of the studies and their level of evidence are figured below (Table 1).

Table 1: Types of the studies and levels of evidence

Level of evidence	Study type
Level I	**Randomised controlled study with effective blinding** and with statistically significant difference. **Cohort study** complying with the above criteria. **Systematic review or meta-analysis** of Level I randomised controlled clinical investigations and homogeneous study results.
Level II	**Randomised controlled study**, with a sound statistical evaluation of study results, however **without effective blinding**. **Cohort study** complying with the above criteria. **Systematic review** of Level II studies or with Level I studies with inconsistent results.
Level III	**Open label case control study** with a sound statistical evaluation, however **without randomisation or blinding**. **Retrospective study** based upon available patient data. **Systematic review or meta-analysis** of Level III studies.
Level IV	**Case series** without statistically justified study population. **Case reports** of one or more single patient treatments. **In vitro or animal testing.**
Level V	**Expert opinion**.

Stage 3: Analysis of the clinical data: Making conclusions of:

- Compliance with essential requirements on performance and safety of the medical device and risk/benefit ratio.
- Content of information materials from the manufacturer (labelling, instructions for use, promotional materials, etc.).
- Residual risks, uncertainties and unanswered questions (incl. rare complications, long-term performance and safety in wide use of the medical device), if these are acceptable for CE marking and need to be focused on in post-market phase.

Stage 4: Clinical evaluation report: Final report contains summary of all relevant data from all parts of technical evaluation.

3 Stage 0: Scoping, Plan

3.1 Safety and Efficiency Requirements as Defined by the Manufacturer

The manufacturer presumes, that the medical device shall provide symptoms alleviation and quality of life improvement in patients with urinary incontinence without any real medical risks for patients if used in accordance with its intended purpose. This presumption is in accordance with the lowest risk class of the medical device. The manufacturer expects a high level of absorption and low level of leakage of urine.

3.2 Description of the Medical Device

General information about the medical device:	
Brand name:	Disposable inserts “Dailee Discreet Premium”
Risk Class:	I
Generic group:	Adult nappy
Variants:	Ultra Mini, 28 pcs / Slim Extra, 28 pcs Mini, 28 pcs / Slim Extra, 8x30 pcs Slim Mini, 28 pcs / Maxi, 28 pcs Slim Mini, 16x30 pcs / Slim Maxi, 28 pcs Normal, 28 pcs / Slim Maxi, 6x30 pcs Slim Normal, 28 pcs / Slim Maxi Plus, 28 pcs Slim Normal, 8x30 pcs / Slim Maxi Plus, 6x30 pcs Extra, 28 pcs / Slim Ultra Mini, 2 pcs Slim Mini, 2 pcs / Slim Normal, 2 pcs Slim Extra, 2 pcs / Slim Maxi, 2 pcs Slim Maxi Plus, 2 pcs / Slim Extra, 1 pc Slim Maxi, 1 pc / Slim Normal, 10 pcs Slim Extra, 10 pcs / Slim Extra Plus, 10 pcs Slim Maxi , 10 pcs / Slim Maxi Plus, 10 pcs
Accessory:	There is no accessory of the medical device.
Life cycle phase:	Medical device CE marked.
Intended use:	Medical device Disposable inserts “Dailee Discreet Premium“ are designed to collect urine . It is predominantly designed to deal with incontinence problems. It has an anatomical shape for perfect fit and maximum comfort. Provides a long-term feeling of drought.
Indications/medical conditions:	The medical device is designed to treat urinary incontinence problems. It deals with symptoms of such

	condition and is not intended to cure the cause. Incontinence is a common and distressing problem, which may have a large impact on quality of life.
Contraindications, precautions and warnings:	There are no known contraindications other than possible allergic reactions to any component of the medical device. No warnings or precautions are needed.
Target group:	The medical device is intended for patients suffering from incontinence problems. Its use is not restricted by age or gender.
Target user:	The device is intended to be use by target population, i.e. laic incontinence patients.
Target area on the human body:	Patient's skin.
Human body contact duration:	Device is being changed for several times a day. Continuous use of devices of the same type is not limited.
Disposability:	The medical device is disposable.
Frequency of application:	According to the patient's needs. It is used several times a day.
Invasiveness / Implantability:	The medical device is not invasive or implantable.
Composition:	Cellulose, PE, non-woven (polypropylene), SAP
Technical specification:	It has an anatomical shape for perfect fit and maximum comfort. The top layer is made by technology that provides long-lasting dryness.
Physically–chemical specification:	The medical device is composed of cellulose and low-density polyethylene. These materials are widely used in medical devices. Description of materials is below in the table.
Sterility:	The medical device is non-sterile or to be sterilized by the user.
Radioactivity:	The medical device is not radioactive.
Mechanism of action and principle of the medical device:	The medical device holds leaky urine . It is applied on the patient instead of normal pants as a leakage protection.
Information on materials coming into the contact with the human body:	Cellulose is well known as one of the most abundant biodegradable materials in nature and has been widely used in medical applications such as wound dressing, tissue engineering, controllable drug delivery system,

	blood purification, etc., due to its biocompatibility, hydrophilicity, biodegradable, nontoxicity and antimicrobial properties. Polyethylene is a thermoplastic polymer with variable crystalline structure and an extremely large range of applications depending on the particular type. It is one of the most widely produced plastics in the world. Polyethylene is nontoxic, non-contaminating and exhibits a high degree of break resistance. It is widely used for medical applications.
Incorporation of a medicinal substance:	The medical device does not incorporate a medicinal substance.
Additional information	
Detailed description of intended benefits for patients and relevant clinical parameters.	Symptoms alleviation, quality of life, conservative low-risk treatment method, high level of absorption, low level of leakage of urine.
Innovation of the product:	There are no novel features in the medical device. The medical device is a standard incontinence device, which has been widely used in the clinical practice.
Is there a previous version of the medical device?	There is no previous version of the medical device.
Is an equivalent medical device used in the clinical evaluation?	The clinical evaluation is based on equivalency demonstration with Dailee Lady Premium (Drylock Technologies). Dailee Discreet Premium is another brand name of Dailee Lady Premium.

3.3 Clinical Development Plan

The clinical evaluation presented hereby is the first clinical evaluation of this medical device. As the next step, the manufacturer shall maintain the PMS system, on which basis a PMCF according to part B of Annex XIV of MDR shall be performed in the future.

3.4 Requirement for Specific Attention

There is no characteristics, indication or target group, which could pose specific concern regarding to performance and/or safety of the medical device under evaluation and which might require specific attention.

3.5 The Risk Management Documents

As part of the safety assessment of the medical device a risk analysis was carried out in accordance with EN ISO 14971:2019 – Medical devices – Application of risk management to medical devices. The risk analysis was performed throughout all phases of the lifecycle of the

medical device by the risk matrix method. Risks have been evaluated and it has been demonstrated that the medical device is not a dangerous product for patient or any other individual. Complete risk analysis is a part of the technical documentation of the medical device and consists of three main parts:

- Risk Management Plan,
- Risk Management Process,
- Risk Management Report.

Altogether risks in 5 life cycle phases have been identified:

- Risks in Design and development phase,
- Risks in Production phase,
- Risks in Packaging and labelling phase,
- Risks in Distribution phase,
- Risks in Using phase.

Risks were assessed and risk matrix was performed, on which basis medium and high risks were identified. As a next step risk control options analysis was performed. Residual risks were evaluated and it was concluded, that the device is not dangerous for patients or other persons. Monitoring of all residual clinical risks is achieved by post-market surveillance of the medical device.

3.6 The Current Knowledge and State of the Art

Medical device “Dailee Discreet Premium” is an adult incontinence aid for urinary leakage. In the Czech Republic, the General Health Insurance Company (GHIC) covers around 230,000 people. In the GHIC catalogue there are over 800 products, including accessories, at no extra charge. GHIC spent about 1.52 billion crowns last year for incontinence aids.

In general, it is necessary to ensure that this type of medical device is sufficient for the absorption and the anatomical structure of the medical device. Devices “Dailee Discreet Premium” are used several times a day. Emphasis is placed on breathability despite the above-mentioned maximum absorption and dryness. This type of medical device is an essential part of care for patients suffering from incontinence or other types of uncontrolled leakage of urine . In particular, the study looked at the use of these medical devices in the elderly, as well as in follow-up care and urology. No allergic reaction to the material used has been demonstrated in any of the studies and no adverse events have been identified. The quality of life of patients using this type of medical device did not decrease significantly, on the contrary, in some serious cases these medical devices contributed to the earlier return to home care. [1-5].

3.7 Data Sources and Types of Data to Be Used in the Clinical Evaluation

Following sources have been chosen for scientific literature searching and other data searching:

- Online database: PubMed.

- Online searching of adverse events reporting (MAUDE, DAEN, RZPRO).
- Unpublished data: non-clinical data (risk management, information materials, pre-clinical evaluation) and clinical data (PMCF study).

3.8 Changes on the Device Made or Planned

The manufacturer has not made and does not plan to make any changes on the device. This statement includes: design, materials, manufacturing processes, information materials etc.

3.9 Post-Market Surveillance

No new clinical uncertainties were concluded out of PMS. PMCF study only confirmed the clinical safety and very low risk of an allergy reaction. One new risk was included into the risk management based on PMS – Wrinkling, rolling, tearing, disintegration of the device. This is only a mechanical problem of the material and does not present any actual health-related risk to be investigated further in PMS. The risk of an allergy reaction is minimal and shall be further observed in the clinical use of the medical device.

Parts of the clinical evaluation, that are being updated:

- The clinical evaluation is updated in whole extent in order to comply with MDR.
- PMS, including PMCF study and vigilance system is evaluated.
- Literature review is updated.

3.10 Extent of Clinical Evidence Needed

Following the MDR, Article 2, paragraph (48) “clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up” are needed as required clinical evidence. Statistically sufficient population sample is needed in clinical data collection in order to assess clinical safety and efficiency.

3.11 The Need of Clinical Investigation

Carrying out of clinical investigation should be considered if at least one of the following aspects is fulfilled (Table 2).

Table 2: Aspects for clinical investigation consideration

Aspect	**Is an aspect fulfilled?**
New design features, including new materials	NO
New intended purposes, including new medical indications, new target populations (age, gender, etc.)	NO
New claims the manufacturer intends to use	NO
New types of users (e.g. lay persons)	NO
Seriousness of direct and/or indirect risks	NO
Contact with mucosal membranes or invasiveness	NO

Increasing duration of use or numbers of re-applications	NO
Incorporation of medicinal substances	NO
Use of animal tissues (other than in contact with intact skin)	NO
Issues raised when medical alternatives with lower risks or more extensive benefits to patients are available or have become newly available	NO
Issues raised when new risks are recognised (including due to progress in medicine, science and technology)	NO
Whether the data of concern are amenable to evaluation through a clinical investigation	NO

Based on the Table 2 it was decided, that the clinical investigation shall not be performed, and the clinical evaluation shall be based on the clinical data from PMS (Post-Market Surveillance) of the evaluated medical device, especially PMCF (Post-Market Clinical Follow-up), supported by the literature review.

3.12 Alternative Treatment Methods for Intended Indications

Below-listed methods are available in the treatment of urinary and fecal incontinence. Some of them treat the cause, others alleviate the symptoms. Medical device under evaluation is intended to treat the symptoms and is not intended to be used as the only method for treating incontinence.

Table 3: Alternative treatment methods. UI = urinary incontinence.

Treatment method	Indications	Description (incl. risks and benefits)
Behavioral techniques	UI	Dietary changes, bladder/bowel training (trying to hold the urine or effort to use the toilet), pelvic floor muscle exercises. This method has no risks but does not treat the problem. It only can lower the symptoms.
Electrical stimulation	UI	Minimally invasive treatment to stimulate nerves and muscles. Electrical stimulation may provide better control over the muscles in order to hold urine . It may be helpful for some kind of patients, but it needs to be several times a month for several months. It is a low risk method. Known risks are pain, wire movement, infection and temporary electric shock-like feeling. However, this method has relatively many contraindications.
Medications	UI	Anti-diarrheal drugs, laxatives, alpha blockers, topical estrogen, anticholinergics. Commonly, medications are reducing spasms that can cause urgency and leakage. Associated risks are dependent on individual medications, the most often risks include: dry mouth, constipation, dry skin, dry eyes, and upset stomach.

		Risks also depend on interactions with other medications.
Pessary	UI	A stiff ring to insert into vagina and wear all day. Pessary offers symptomatic improvement for women. Since this method is invasive it also has various risks such as: open sores in the vaginal wall, bleeding, wearing away of the vaginal wall, fistula between the vagina and the rectum, bulging of the rectum against the vaginal wall.
Non-surgical interventional therapy	UI	For example, bulking material injections, which are not that effective and botox injections, which are associated with such risks as: urinary tract infections, blood in the urine, damage to the bladder, injury to the bowels etc. Benefit of these method is a causal treatment of incontinence. The bulking material helps keep the urethra closed and reduce urine leakage. Botox might be helpful for treating an overactive bladder.
Surgical methods	UI	Sling methods, bladder neck suspension, prolapse surgery, sphincteroplasty, sphincter replacement or repair, colostomy. Surgical methods are commonly connected with high risks and are recommended as one of the last options. Specific risks are: urinary retention, development of overactive bladder, infections, difficult or painful intercourse and many others. The benefit of surgical methods is causal treatment.
Catheter	UI	Tube to be inserted into the bladder in order to drain bladder completely. This method is not patient-friendly and brings many risks, e.g.: bleeding, urethritis, stricture, creation of a false passage, epididymitis, stones, pain etc. The benefit of this method lies in a good control of patients over the incontinence problems.

3.13 Demonstration of Equivalence

Table 4: Demonstration of equivalence of Dailee Discreet Premium and Dailee Lady Premium based on MDR, Annex XIV, Part A, paragraph 3

Area	Characteristic	Fulfillment
Technical	is of similar design	YES
	is used under similar conditions of use	YES
	has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms	YES
	uses similar deployment methods, where relevant	YES
	has similar principles of operation and critical performance requirements	YES
Biological	uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of	YES

	contact and similar release characteristics of substances, including degradation products and leachables	
Clinical	used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology	YES
	has the same kind of user	YES
	has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose	YES

4 Stage 1: Identification of Pertinent Data

4.1 Data Generated and Held by the Manufacturer

Data generated and held by the manufacturer can be divided into clinical and non-clinical data:

Clinical data sources: PMCF report, PMS system, Vigilance system.

Non-clinical data sources: Risk management, Labelling, Device description and specification, Classification of medical device, Design and manufacturing information, Packaging procedure.

4.2 Data Retrieved from Literature

The collection and identification of data for this section has been achieved by scientific literature searching. The aim of searching was to retrieve clinical data relevant to the medical device. Both desirable and undesirable data were used to avoid any bias.

The scientific literature was searched using the databases Web of Science, PubMed, Summon, Google Scholar, Cochrane Controlled Clinical Trials Register and key words: “adult incontinence inserts”, “incontinence aids”, “medical devices for light Incontinence”.

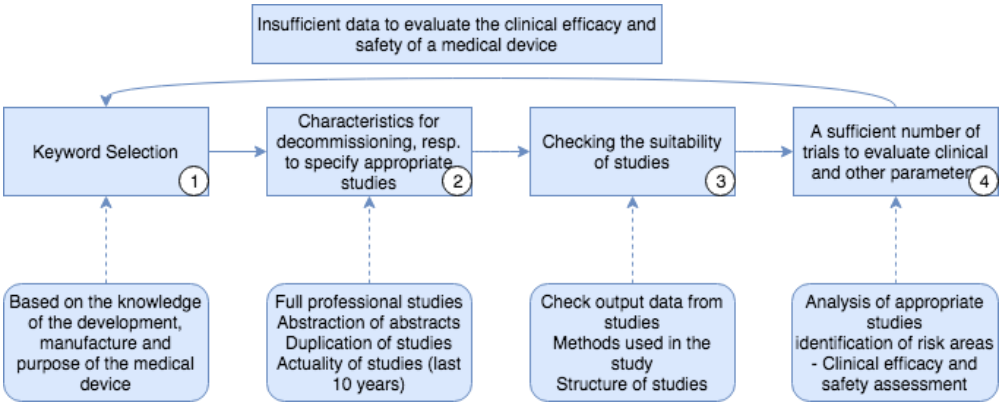


Figure 2: Methodology of searching study

In the literature searching, studies were searched according to several keywords based on the graph below.

The keyword selection process was based on the flowchart (Figure 3: Keyword Selection).

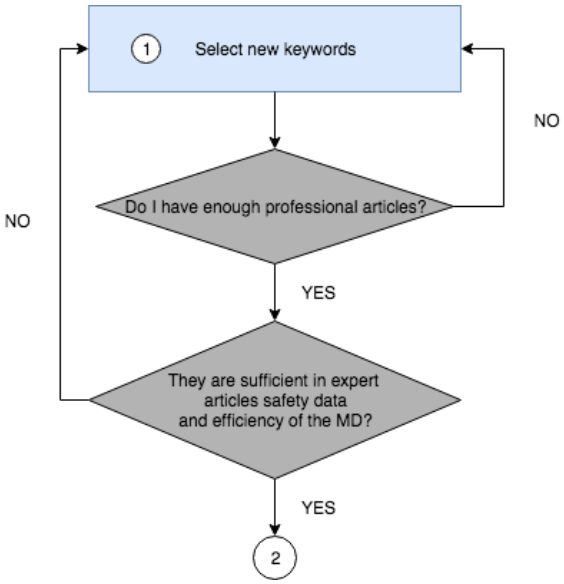


Figure 3: Keyword Selection

5 Stage 2: Assessment of Relevant Data

In this phase evaluators assess final data and determines their weight. Data weight depends on their relevance to the medical device under evaluation and a level of evidence of source studies.

5.1 Relevant Data Appraisal Plan

Relevant data appraisal plan includes selection of criteria to determine:

- level of evidence (Table 1);
- relevance of data to the medical device under evaluation – on the basis of its characteristics and intended use; and
- contribution of data to the clinical evaluation by their weight (Table 5).

5.1.1 Scientific Literature Data

Studies found in previous phase were assessed and only such studies, which contain data relevant for the clinical evaluation were included. Exclusion criteria were as follows:

- Based on field specifications.
- Duplication of studies.
- Incompleteness of study:
  - only abstract available;
  - unspecified population, indications or used methods;
  - missing clinical outcomes or other data for evaluation.
- Insufficient data:
  - different patient, population or indications.

Weight of data retrieved from scientific literature was assessed by following methodology (Table 4).

Table 4: Data weighting methodology. Reference: Document GHTF SG5/N2R8:2007.

Suitability Criteria	Description	Weight	Grading System
Appropriate device	Were the data generated from the device in question?	A1 A2 A3	Actual device Comparable device Other device
Appropriate device application	Was the device used for the same intended use?	B1 B2 B3	Same use Minor deviation Major deviation
Appropriate patient group	Were the data generated from a patient group that is representative of the intended treatment population and clinical condition?	C1 C2 C3	Applicable Limited Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	D1 D2 D3	High quality Minor deficiencies Insufficient information

5.1.2 Other Data Sources

Clinical data sources: PMCF report, PMS system, Vigilance system.

Non-clinical data sources: Risk management, Labelling, Device description and specification, Classification of medical device, Design and manufacturing information, Packaging procedure.

5.2 Conduct of the Appraisal

5.2.1 Methodological Quality and Scientific Validity Evaluation

An exclusion and appraisal of studies led to identification of 13 key studies, which shall be used for data analysis in the next phase. These studies are listed and weighted in 5.

Table 5: Key studies overview

Year	Study	Level of evidence	Weight of data	Reference
2015	Knowledge, Attitudes, Beliefs, and Practices in Registered Nurses and Care Aids About Urinary Incontinence in Korean Nursing Homes	*	*	[1]
2011	In-Hospital Use of Continence Aids and New-Onset Urinary Incontinence in Adults Aged 70 and Older	*	*	[2]
2002	Incontinence aids in Sweden	*	*	[3]
1990	The Prevalence of Urinary Incontinence and Use of Incontinence Aids in 85-year-old Men and Women	*	*	[4]

1992	An evaluation of the acceptability of incontinence aids used by 85-year-old men and women	*	*	[5]
2010	Improving diaper design to address incontinence associated dermatitis	IV	A2, B1, C3, D2	[6]
2001	Effects of Breathable Medical Devices for Light Incontinence	I	A2, B1, C1, D1	[7]
2004	The vulvar skin microenvironment: influence of different panty liners on temperature, pH and microflora	II	A2, B1, C1, D1	[8]
2006	Prevalence and correlates of perineal dermatitis in nursing home residents	III	A3, B3, C1, D2	[9]
2011	Incontinence associated dermatitis in a long-term acute care facility	III	A3, B3, C2, D2	[10]
2011	Incontinence-associated dermatitis in critically ill adults	III	A3, B3, C3, D2	[11]
2007	Perineal dermatitis in critical care patients	III	A3, B3, C3, D2	[12]
2008	Absorbent product use and incontinence associated dermatitis in community dwelling persons with fecal incontinence	II	A3, B2, C1, D2	[13]

* These studies were only used for the current state of the art description, not for the clinical data analysis in Stage 3.

Clinical data sources of the evaluated medical device (especially PMCF study) are considered as the most relevant with the highest level of evidence. Non-clinical data sources of the medical device under evaluation are considered only as supportive as these do not provide any clinical evidence.

6 Stage 3: Analysis of the Clinical Data

6.1 Scientific Literature Data Analysis

Typical side-effect of incontinence devices is dermatitis (IAD – incontinence associated dermatitis). It affects between 5.7% to over 42% of incontinence patients. Occurrence is connected with higher age. Elderly people have weaker epidermal barrier and lower regeneration capacity [6].

Occurrence of dermatitis depends on permeability of incontinence devices. It has been shown in double-blinded controlled clinical study on newborn children. Severe dermatitis was found in 38% and 50% in permeable and impermeable devices, respectively [7].

In another study with 102 female patients 34% women wearing impermeable inserts answered, that they felt wet, against 13% women wearing permeable inserts [8].

According to Bliss et al the incidence of IAD during the 6 weeks observation period in 981 patients was 3.4% [9]. Another study counting 132 patients with observation period 13.5 days (median) showed the IAD incidence 7.6% [10].

In a study observing fecal incontinence only was IAD incidence 36% [11]. Next study with fecal incontinence only was IAD incidence 50% in short-term observation (<14 days) and 19% in a long-term observation (>14 days) [12]. However, these results were observed in a critical care unit.

Approximately half (52%) of 96 community-living people with fecal incontinence reported experiencing incontinence-associated perineal skin damage. Skin redness without broken skin was the most common form of skin damage (37% of respondents), followed by a rash (18%), broken skin (13%) and bleeding (9%) [13].

6.2 Clinical Data of the evaluated Medical Device

6.2.1 Post-Market Clinical Follow-up Study

PMCF study was conducted in 2018 and PMCF report was issued in 2019. The collection of clinical data was realized in several health care centers in Czech Republic. Data of adult pants and diapers were retrieved from 228 patients out of which 89 used the equivalent medical device “Dailee Lady Premium”.

Average age was 88.57 $\pm$ 8.86 years (median = 90.00 years, mode = 96.00 years). Minimal age was 73 years and maximal age was 98 years. Questionnaires were filled by health care personnel (55.7%), patient themselves (1.75%) or such information is missing (42.54%).

In a statistical assessment of clinical data following criteria were included:

Assessment of Absorption

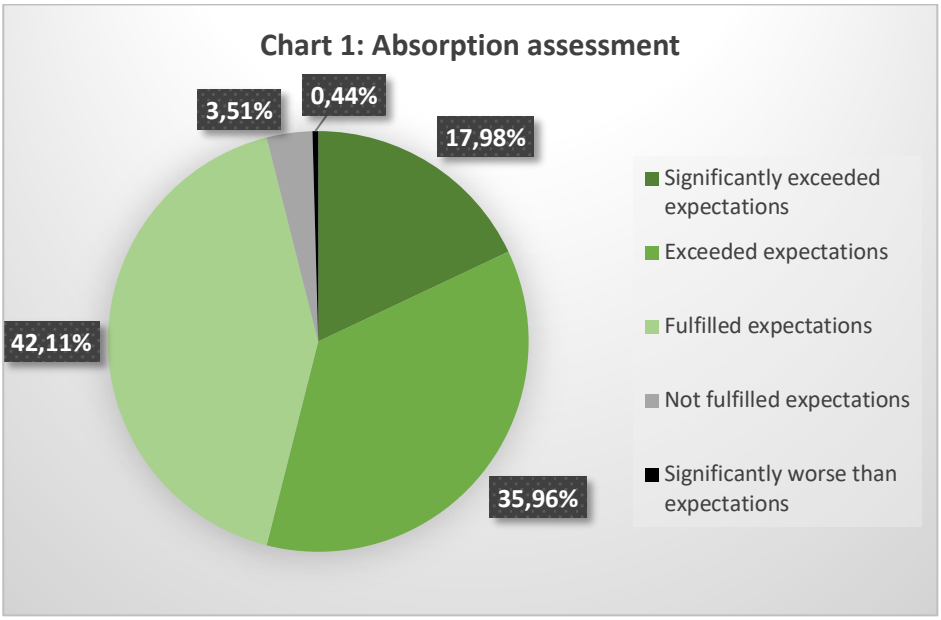
Absorption is assessed in tables and chart below. 228 out of 228 patients answered question related to absorption assessment. It can be concluded, that over 90% of cases of clinical use of Medical Devices for Light Incontinence provided satisfying absorption level. Since the difference between average and median exceeds 10% normal distribution is not considered.

Table 6: Absorption – ratings

Score	Rating	Total	Percent
1	Significantly exceeded expectations	41	17.98%
2	Exceeded expectations	82	35.96%
3	Fulfilled expectations	96	42.11%
4	Not fulfilled expectations	8	3.51%
5	Significantly worse than expectations	1	0.44%

Table 7: Absorption – evaluation

	Average	Deviation	Median	Mode
Score	2.32	0.82	2.00	3.00



Assessment of Leakage

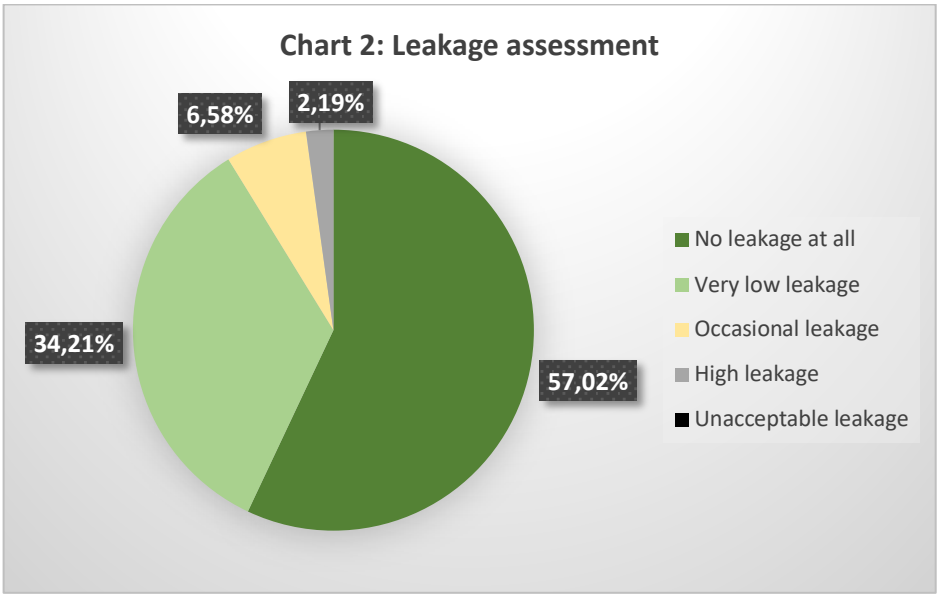
Leakage is assessed in tables and chart below. 228 out of 228 patients answered question related to leakage assessment. It can be concluded, that in most of the cases of clinical use of Medical Devices for Light Incontinence provided satisfying level of urine trapping. Since the difference between average and median does not exceed 10% normal distribution is considered.

Table 8: Leakage – ratings

Score	Rating	Total	Percent
1	No leakage at all	130	57.02%
2	Very low leakage	78	34.21%
3	Occasional leakage	15	6.58%
4	High leakage	5	2.19%
5	Unacceptable leakage	0	0.00%

Table 9: Leakage – evaluation

	Average	Deviation	Median	Mode
Score	1.54	0.72	1.00	1.00



Assessment of Fixation

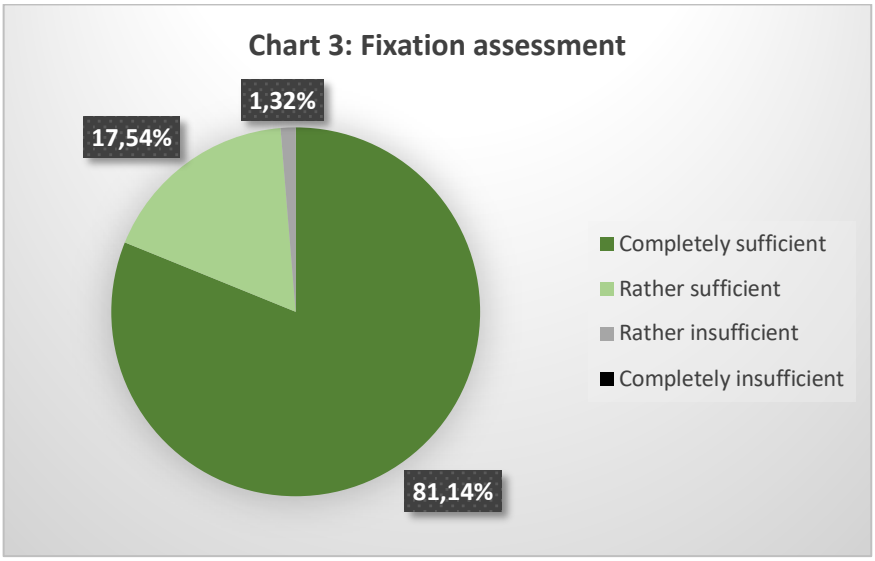
Fixation is assessed in tables and chart below. 228 out of 228 patients answered question related to fixation assessment. It can be concluded, that in over 90% of cases of clinical use of Medical Devices for Light Incontinence satisfying fixation was achieved. Since the difference between average and median exceeds 10% normal distribution is not considered.

Table 10: Fixation – ratings

Score	Rating	Total	Percent
1	Completely sufficient	185	81.14%
2	Rather sufficient	40	17.54%
3	Rather insufficient	3	1.32%
4	Completely insufficient	0	0.00%
5	Unacceptable leakage	0	0.00%

Table 11: Fixation – evaluation

	Average	Deviation	Median	Mode
Score	1.20	0.43	1.00	1.00



Assessment of Changing

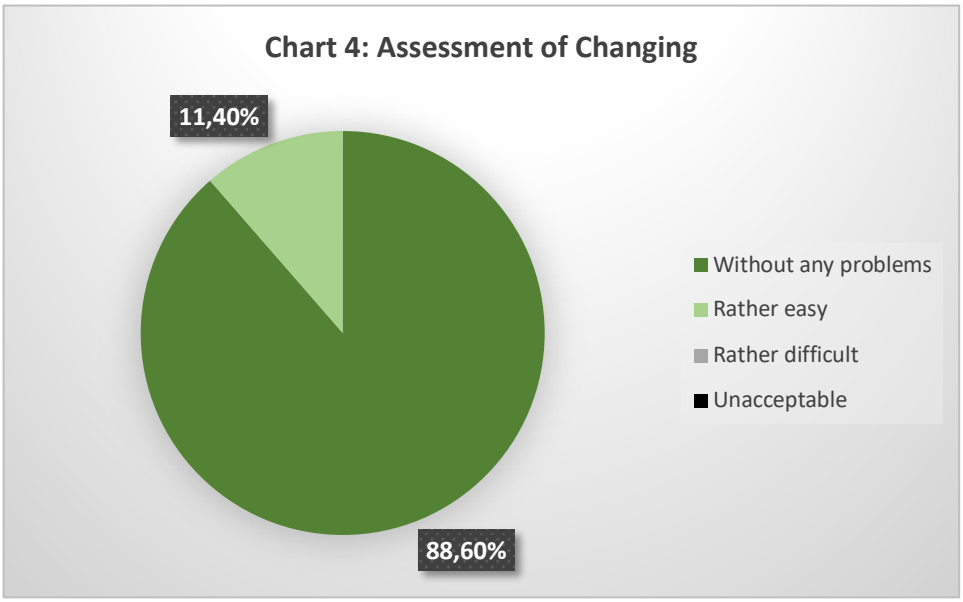
Changing is assessed in tables and chart below. 228 out of 228 patients answered question related to change assessment. It can be concluded, that in all of the cases cases of clinical use of Medical Devices for Light Incontinence patients were satisfied with the ease of changing.

Table 12: Changing – ratings

Score	Rating	Total	Percent
1	Without any problems	202	88.60%
2	Rather easy	26	11.40%
3	Rather difficult	0	0.00%
4	Unacceptable	0	0.00%

Table 13: Changing – evaluation

	Average	Deviation	Median	Mode
Score	1.11	0.32	1.00	1.00



Assessment of Fulfillment of Intended Purpose

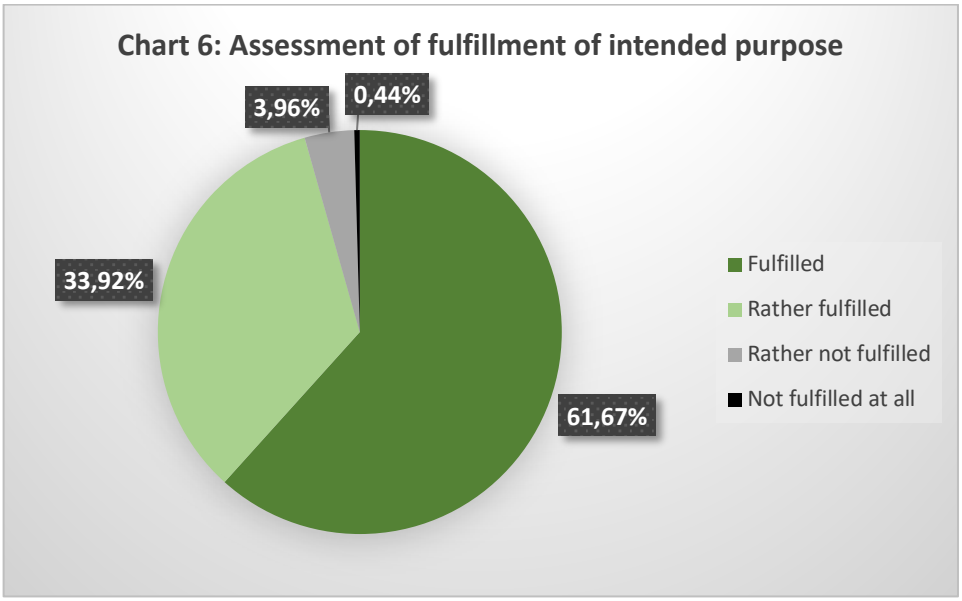
Fulfillment of intended purpose is assessed in tables and chart below. 227 out of 228 patients answered question related to assessment of fulfillment of intended purpose. It can be concluded, that in over 90% of cases of clinical use of Medical Devices for Light Incontinence intended purpose was fulfilled. Since the difference between average and median exceeds 10% normal distribution is not considered.

Table 14: Fulfillment of intended purpose – ratings

Score	Rating	Total	Percent
1	Fulfilled	140	61.67%
2	Rather fulfilled	77	33.92%
3	Rather not fulfilled	9	3.96%
4	Not fulfilled at all	1	0.44%

Table 15: Fulfillment of intended purpose – evaluation

	Average	Deviation	Median	Mode
Score	1.43	0.59	1.00	1.00



Assessment of Allergic Reactions and Adverse Events

Tables below summarize reporting of allergic reactions and adverse events in the patients in PMCF study. Occurrence is figured in chart 7 and individual reports are described in tables 17 and 18.

Table 16: Occurrence of allergic reactions

	Yes	No
Allergic reaction	1	227
Percent	0.44 %	99.56 %

Table 17: Description of allergic reactions

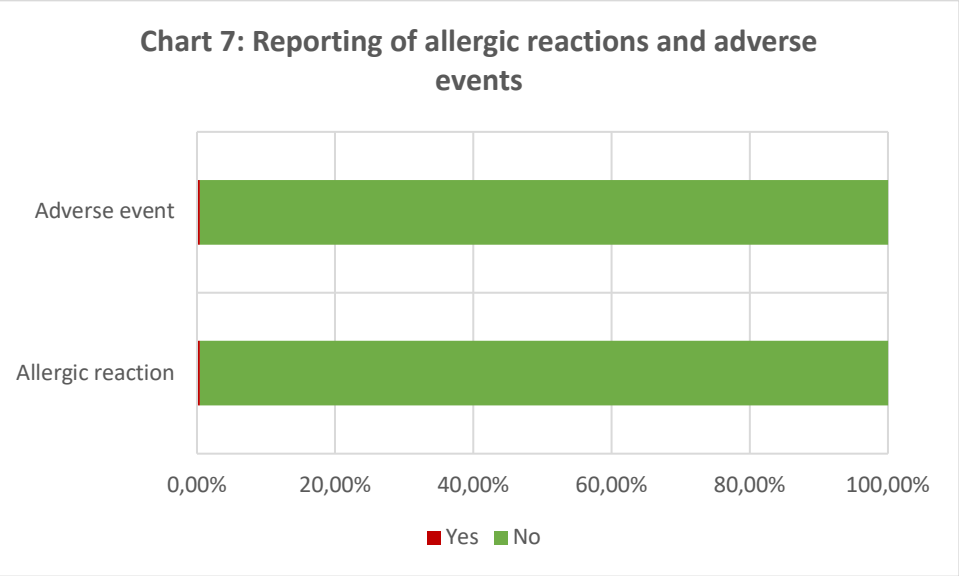
Description of allergic reaction	Occurrence
Not specified	1x

Table 58: Occurrence of adverse events

	Yes	No
Adverse event	1	227
Percent	0.44 %	99.56 %

Table 19: Description of adverse events

Description of adverse events	Occurrence
Strong odor	1x



It can be seen that only small number of patients had allergic reaction or adverse event and none of the reports of adverse event relates to conditions defined as “adverse event” or “serious adverse event” in MDR. Reports of adverse events relate to standard side effects or technical problems with the device. These problems have no impact on health of a patient or any other person.

6.2.2 PMS System and Vigilance System

Based on post-market surveillance and vigilance system of the manufacturer no adverse events or health-related problems linked to the evaluated medical device were observed. The manufacturer has the PMS System as well as the Vigilance System implemented, updated and documented as part of the technical documentation.

6.3 Other Sources Data Analysis

6.3.1 Adverse Events Reports

For a safety and efficacy assessment based on the vigilance system, the Manufacturer and User Device Facility (MAUDE)[1] database was used. It is the Food and Drug Administration (FDA) database of adverse events.

Within the database reports of adverse events related to the use of the medical device were sought. The database contains information from users since 1991, information from distributors since 1993, and information from manufacturers since 1996.

As a keyword "*incontinence pads*" was used for searching. No adverse events were found.

As next, adverse events were searched in the Database of Adverse Event Notifications (DAEN)[2]. This database contains information of adverse events reports of medical devices in Australia since 2012. It is the database of Therapeutic Goods Administration (TGA), which is the regulatory agency of medical devices and medicinal products in Australia.

As a keyword "*incontinence pads*" was used for searching. No adverse events were found.

Furthermore, Registry of Medical Devices (RZPRO) of State Institute for Drug Control of Czech Republic was used to search Field safety notices. When searched for the manufacturer by keywords "*inkontinence, inkontinenční*", no notices have been found.

6.3.2 Risk Management

As part of the safety assessment of the medical device, a risk analysis was carried out in accordance with EN ISO 14971:2019 – Medical devices – Application of risk management to medical devices. Risk analysis is linked with this clinical evaluation in full extent.

There were risks identified throughout the medical device lifecycle. The risk matrix analysis was carried out and each risk was evaluated individually. It was evaluated, that all known risks are acceptable and there are no unacceptable residual risks for the medical device to be used in clinical practice.

6.3.3 Risk/Benefit Ratio Evaluation

Based on the clinical data of the evaluated device (especially PMCF study) and literature review and outcomes of the risk analysis it was evaluated, that **the risks of the medical device Disposable inserts „Dailee Discreet Premium" are compensated by the patient's benefits**. Thus, risk/benefit ratio is acceptable.

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
[2] https://apps.tga.gov.au/prod/DEVICES/

Table 20: Risk/benefit ratio assessment

Clinical data – PMCF	**Risk management, PMCF**
Absorption – over 90% of cases of clinical use of Changing Pads provided satisfying absorption level.	Risks in design and development phase, production phase, packaging and labelling phase and distribution phase are minimal. Possible clinical risks are as follows: strong odor, redness. These events do not present a serious risk for patient or other persons. Allergic reaction are the only possible clinical risks, but its incidence is minimal (0.44%).
Leakage – over 90% of cases provided satisfying leakage level.	
Fixation – over 90% patients were satisfied with the comfort.	
Changing – all 100% patients were satisfied with the ease of changing.	
In over 90% of cases the intended purpose of the medical device was fulfilled.	

6.3.4 Pre-clinical Evaluation

In the preclinical evaluation of the medical device were performed: in vitro cytotoxicity test and skin irritation test. Preclinical tests were performed in 2017 according to the following standards:

- EN ISO 10993-1:2020: Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process.
- EN ISO 10993-5:2010: Biological evaluation of medical devices - Part 5: Cytotoxicity tests: in vitro methods).
- EN ISO 10993-10:2014: Biological evaluation of medical devices - Part 10: Examination of irritation and sensitization.

6.3.5 Information Materials Supplied by the Manufacturer

An exception for non-issuance of instructions for use was applied. All information necessary for a proper use of the device are contained in labels.

6.4 Declaration of the Manufacturer

The manufacturer hereby declares, that:

- The medical device complies with safety and efficiency requirements defined in the clinical evaluation plan (Stage 0).
- The medical device is designed in such way, that the risk of its misusing is minimalized.
- Design of the medical device is adjusted for intended users.

6.5 Determination of Compliance with Essential Requirement on Safety and Performance

Essential requirement on safety and performance is in the first paragraph of MDR, Annex I:

Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Based on the clinical data of the medical device, supportive non-clinical data and data from literature review regarding other methods of treatment of similar medical conditions it can be concluded, that the medical device is designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose.

6.6 Assessment of Data Sufficiency

Since there were no gaps or lack of data quantity and quality, it was decided by the evaluator, that the extent of the clinical evaluation is sufficient for a demonstration of compliance with essential requirements on the medical device, therefore required safety and performance demonstration is achieved.

6.7 Next Clinical Evaluation

Next issue of the clinical evaluation shall be carried out 5 years after this clinical evaluation, i.e. in 2029. This frequency of update was established based on risk class of medical device and supposing that medical device is not expected to carry significant risks and similar medical devices are well established in clinical practice.

The clinical evaluation shall be revised in following cases:

- changes in legislation or related technical standards;
- based on an updated collection of clinical data (from the post-market surveillance phase);
- changes on the product; or
- based on post-market activities of the manufacturer.

7 Stage 4: The Clinical Evaluation Report

<table>
<tr><th>Content</th><th>Description, declarations, results, conclusions</th></tr>
<tr><td>1. Summary</td><td>The clinical evaluation of the medical device Disposable inserts „Dailee Discreet Premium“ performed under the MEDDEV 2.7/1 rev. 4 methodology demonstrates safety of the medical device regarding the use on target population and in accordance with the intended use determined by the manufacturer; and efficiency for the treatment of incontinence problems. The clinical data were obtained on the basis of clinical data of the medical device (especially from PMCF study) and literature review.</td></tr>
<tr><td>2. Scope of the clinical evaluation</td><td>Manufacturer:
Drylock technologies, s.r.o.
Brand name:
Disposable inserts “Dailee Discreet Premium“
Variants:
<table>
<tr><td>Ultra Mini, 28 pcs</td><td>Slim Extra, 28 pcs</td></tr>
<tr><td>Mini, 28 pcs</td><td>Slim Extra, 8x30 pcs</td></tr>
<tr><td>Slim Mini, 28 pcs</td><td>Maxi, 28 pcs</td></tr>
<tr><td>Slim Mini, 16x30 pcs</td><td>Slim Maxi, 28 pcs</td></tr>
<tr><td>Normal, 28 pcs</td><td>Slim Maxi, 6x30 pcs</td></tr>
<tr><td>Slim Normal, 28 pcs</td><td>Slim Maxi Plus, 28 pcs</td></tr>
<tr><td>Slim Normal, 8x30 pcs</td><td>Slim Maxi Plus, 6x30 pcs</td></tr>
<tr><td>Extra, 28 pcs</td><td>Slim Ultra Mini, 2 pcs</td></tr>
<tr><td>Slim Mini, 2 pcs</td><td>Slim Normal, 2 pcs</td></tr>
<tr><td>Slim Extra, 2 pcs</td><td>Slim Maxi, 2 pcs</td></tr>
<tr><td>Slim Maxi Plus, 2 pcs</td><td>Slim Extra, 1 pc</td></tr>
<tr><td>Slim Maxi, 1 pc</td><td>Slim Normal, 10 pcs</td></tr>
<tr><td>Slim Extra, 10 pcs</td><td>Slim Extra Plus, 10 pcs</td></tr>
<tr><td>Slim Maxi , 10 pcs</td><td>Slim Maxi Plus, 10 pcs</td></tr>
</table>
Class:
I.
Intended use:
Medical device Disposable inserts “Dailee Discreet Premium“ is designed to collect urine . It is predominantly designed to deal with incontinence problems. It has an anatomical shape for perfect fit and maximum comfort. Provides a long-term feeling of drought.
Indications:
The medical device is designed to treat urinary incontinence problems. It deals with symptoms of such condition and is not intended to cure the cause. Incontinence is a common and distressing problem, which may have a large impact on quality of life.</td></tr>
</table>

	Contraindications: There are no known contraindications other than possible allergic reactions to any component of the medical device. No warnings or precautions are needed. **Target group**: The medical device is intended for patients suffering from incontinence problems. Its use is not restricted by age or gender. **Target user**: The device is intended to be use by target population, i.e. laic incontinence patients. **Application site in the body**: Patient's skin. The medical device is intended for **single use.** The medical device is **non-sterile** or **to be sterilized** by the user. The medical device is **neither invasive nor implantable**. The medical device is **not radioactive**. The medical device **does not incorporate a medicinal substance**. **Mechanism of action**: The medical device holds leaky urine . It is applied on the patient instead of normal pants as a leakage protection. **Composition**: Cellulose, PE, non-woven (polypropylene), SAP. **Safety and efficiency requirements as defined by the manufacturer**: The manufacturer presumes, that the medical device shall provide symptoms alleviation and quality of life improvement in patients with urinary incontinence without any real medical risks for patients if used in accordance with its intended purpose. This presumption is in accordance with the lowest risk class of the medical device. The manufacturer expects a high level of absorption and low level of leakage of urine. **Lifecycle phase**: CE marked.
3. Clinical background, current knowledge, state of the art	Medical device "Dailee Discreet Premium" is an adult incontinence aid for urinary leakage. In the Czech Republic, the General Health Insurance Company (GHIC) covers around 230,000 people. In the GHIC catalogue there are over 800 products, including accessories, at no extra charge. GHIC spent about 1.52 billion crowns last year for incontinence aids. In general, it is necessary to ensure that this type of medical device is sufficient for the absorption and the anatomical structure of the medical device. Devices "Dailee Discreet Premium" are used several times a day. Emphasis is placed on breathability despite the above-mentioned

	maximum absorption and dryness. This type of medical device is an essential part of care for patients suffering from incontinence or other types of uncontrolled leakage of urine . In particular, the study looked at the use of these medical devices in the elderly, as well as in follow-up care and urology. No allergic reaction to the material used has been demonstrated in any of the studies and no adverse events have been identified. The quality of life of patients using this type of medical device did not decrease significantly, on the contrary, in some serious cases these medical devices contributed to the earlier return to home care. [1–5].
4. Device under evaluation	
4.1 Type of evaluation	The clinical evaluation was performed in accordance with MEDDEV 2.7/1 rev. 4. The clinical evaluation was performed on the basis of: 1. clinical data available for the evaluated device; and 2. the literature review.
4.2 Clinical data generated and held by the manufacturer	**1. PMCF Study:** PMCF study was conducted in 2018 and PMCF report was issued in 2019. The collection of clinical data was realized in several health care centers in Czech Republic. Data of adult pants and diapers were retrieved from 228 patients out of which 89 used the evaluated medical device “Dailee Discreet Premium”. Average age was 88.57 ± 8.86 years (median = 90.00 years, mode = 96.00 years). Minimal age was 73 years and maximal age was 98 years. Questionnaires were filled by health care personnel (55.70%), patient themselves (1.75%) or such information is missing (42.54%). In a statistical assessment of clinical data following criteria were included: **Assessment of Absorption:** 228 out of 228 patients answered question related to absorption assessment. It can be concluded, that over 90% of cases of clinical use of Medical Devices for Light Incontinence provided satisfying absorption level. **Assessment of Leakage:** 228 out of 228 patients answered question related to leakage assessment. It can be concluded, that in most of the cases of clinical use of Medical Devices for Light Incontinence provided satisfying level of urine trapping. **Assessment of Fixation**

	228 out of 228 patients answered question related to fixation assessment. It can be concluded, that in over 90% of cases of clinical use of Medical Devices for Light Incontinence satisfying fixation was achieved. **Assessment of Changing** 228 out of 228 patients answered question related to change assessment. It can be concluded, that in over 90% of cases of clinical use of Medical Devices for Light Incontinence patients were satisfied with the ease of changing. **Assessment of Fulfillment of Intended Purpose** 227 out of 228 patients answered question related to assessment of fulfillment of intended purpose. It can be concluded, that in over 90% of cases of clinical use of Medical Devices for Light Incontinence intended purpose was fulfilled. **Adverse Events and Allergic Reactions:** Only small number of patients had allergic reaction or adverse event and none of the reports of adverse event relates to conditions defined as "adverse event" or "serious adverse event" in the MDR. Reports of adverse events relate to standard side effects or technical problems with the device. These problems have no impact on health of a patient or any other person. **2. PMS System and Vigilance System:** Based on post-market surveillance and vigilance system of the manufacturer no adverse events or health-related problems linked to the evaluated medical device were observed. The manufacturer has the PMS System as well as the Vigilance System implemented, updated and documented as part of the technical documentation
4.3 Clinical data from literature	Typical side-effect of incontinence devices is dermatitis (IAD – incontinence associated dermatitis). It affects between 5.7% to over 42% of incontinence patients. Occurrence is connected with higher age. Elderly people have weaker epidermal barrier and lower regeneration capacity [6]. Occurrence of dermatitis depends on permeability of incontinence devices. It has been shown in double-blinded controlled clinical study on newborn children. Severe dermatitis was found in 38% and 50% in permeable and impermeable devices, respectively [7]. In another study with 102 female patients 34% women wearing impermeable inserts answered, that they felt wet, against 13% women wearing permeable inserts [8].

<table>
<tr><td></td><td>According to Bliss et al the incidence of IAD during the 6 weeks observation period in 981 patients was 3.4% [9]. Another study counting 132 patients with observation period 13.5 days (median) showed the IAD incidence 7.6% [10].

In a study observing fecal incontinence only was IAD incidence 36% [11]. Next study with fecal incontinence only was IAD incidence 50% in short-term observation (<14 days) and 19% in a long-term observation (>14 days) [12]. However, these results were observed in a critical care unit.

Approximately half (52%) of 96 community-living people with fecal incontinence reported experiencing incontinence-associated perineal skin damage. Skin redness without broken skin was the most common form of skin damage (37% of respondents), followed by a rash (18%), broken skin (13%) and bleeding (9%) [13].</td></tr>
<tr><td>4.4 Summary and appraisal of clinical data</td><td>Clinical data sources of the evaluated medical device (especially PMCF study) are considered as the most relevant with the highest level of evidence. Non-clinical data sources of the medical device under evaluation are considered only as supportive as these do not provide any clinical evidence.

Clinical data from scientific literature are appraised below. The scale of level of evidence is on I–V and weight of data on A1–3, B1–3, C1–3 and D1–3. The lowest numbers suggest highest level/weight.

<table>
<tr><th>Year</th><th>Level of evidence</th><th>Weight of data</th><th>Reference</th></tr>
<tr><td>2010</td><td>IV</td><td>A2, B1, C3, D2</td><td>[6]</td></tr>
<tr><td>2001</td><td>I</td><td>A2, B1, C1, D1</td><td>[7]</td></tr>
<tr><td>2004</td><td>II</td><td>A2, B1, C1, D1</td><td>[8]</td></tr>
<tr><td>2006</td><td>III</td><td>A3, B3, C1, D2</td><td>[9]</td></tr>
<tr><td>2011</td><td>III</td><td>A3, B3, C2, D2</td><td>[10]</td></tr>
<tr><td>2011</td><td>III</td><td>A3, B3, C3, D2</td><td>[11]</td></tr>
<tr><td>2007</td><td>III</td><td>A3, B3, C3, D2</td><td>[12]</td></tr>
<tr><td>2008</td><td>II</td><td>A3, B2, C1, D2</td><td>[13]</td></tr>
</table>
</td></tr>
<tr><td>4. Requirement on safety and performance</td><td>Essential requirement on safety and performance is in the first paragraph of MDR, Annex I:

Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level</td></tr>
</table>

	of protection of health and safety, taking into account the generally acknowledged state of the art Based on the clinical data of the medical device, supportive non-clinical data and data from literature review regarding other methods of treatment of similar medical conditions it can be concluded, that the medical device is designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose.
5. Conclusions	Clinical evaluation has demonstrated the efficacy of the evaluated medical device, the safety of the health of a person for use in the intended purpose, that is to say, within the meaning of MDR, **safety and efficiency** of the evaluated medical device when used under the specified conditions and for the intended purpose of use. The medical device does not endanger the clinical condition or the safety of patients or other persons. Any side effects of an investigational medical device represent only the minimum acceptable risk compared to the expected compensatory effects of disability. The assessed medical device is in accordance with the MDR on the basis of the clinical evaluation **safe and effective.** For the evaluated medical device, a systematic procedure for evaluating the experience gained with the manufactured packaging after its marketing is introduced and this procedure is regularly updated. Clinical evaluation and documentation are being actively updated using data from after-sales supervision and traceability of medical devices after they are marketed. The procedures for legal updates are dealt with in a conformity assessment document of the medical device marked "After-Sales Surveillance and Traceability".
6. Date of the next clinical evaluation	Next issue of the clinical evaluation shall be carried out 5 years after this clinical evaluation, i.e. in 2029. This frequency of update was established based on risk class of medical device and supposing that medical device is not expected to carry significant risks and similar medical devices are well established in clinical practice. The clinical evaluation shall be revised in following cases: - changes in legislation or related technical standards;

	- based on an updated collection of clinical data (from the post-market surveillance phase); - changes on the product; or - based on post-market activities of the manufacturer.
7. Dates and signatures	**Binding opinion of the expert evaluator:** The expert evaluator hereby agrees with the clinical evaluation report content and declares, that clinical evaluation demonstrates safety and efficiency of the medical device under evaluation. In Prague on 17. 12. 2024 Prof. MUDr. Michal Holub, Ph.D. ..... prof. MUDr. Michal Holub, Ph.D. Expert evaluator **Contracting authority of the clinical evaluation:** In Hrádek nad Nisou on 17/12/2024 drylock TECHNOLOGIES Drylock Technologies s.r.o. Vlámská 801 CZ 463 34 Hrádek nad Nisou .....IČ: 25411411 DIČ: CZ25411411 -5- Quality Manager Drylock Technologies
8. Qualification of evaluators	**Name of the evaluator:** prof. MUDr. Michal Holub, Ph.D. **Professional experience:** 30 years of professional practice, 1st degree paediatrics, specialized attestation of communicable diseases, professional competence of infectious medicine. Experience with research projects and clinical trials. Workplace: NsP Kladno, General University Hospital in Prague, Na Bulovce Hospital, Wadsworth Center, Military University Hospital Prague. The evaluator participated in the development and clinical evaluation of medical devices in the past and, in view of the knowledge of the medical device under assessment.

8 References

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