EU Quality Management System Certificate

Certificate no.:
10000376655-PA-NoMA-DNK

Initial certification date:
26 August 2021

Valid Until:
26 August 2026

This is to certify that the quality system of

Coloplast A/S

Holtedam 1, 3050 Humlebaek, Denmark

SRN: NA

For design, production and final product inspection/testing of:

Foam wound dressings, Foam wound dressings with silver, Catheters for intermittent catherization, Surgical accessories, Urological stents, Penile implants, Penile implant accessories, Drainage bags, Endourological instruments, Surgical Mesh, Single Incision Sling System and Urine bags.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 25 October 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Alessandra Rinna
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	5254234	26 August 2021
1.0	Addition of Speedicath control	2499147	17 December 2021
2.0	Addition of Furlow	2499161	27 December 2021
3.0	Addition of Biosoft duo	2522909	03 February 2022
4.0	Blockchain data Changes	NA	03 February 2022
5.0	Addition of Titan and Titan Accessories	2522908	06 April 2022
6.0	Revision of wording and product name on certificate	2703041	06 May 2022
7.0	Addition of drainage bags	2707869	16 May 2022
8.0	Editorial change	NA	30 May 2022
9.0	Addition of Steerable Pusher and Hybrid Guidewire	2499146	17 June 2022
10.0	Addition of Biatain Ag Adhesive Biatain Ag Non-Adhesive and Biatain Silicone Ag	2522905	30 June 2022
11.0	Editing Furlow to be defined as reusable surgical instruments. Include Rossello and Brooks Dilator to reusable surgical instrument product list.	2706360	13 July 2022
12.0	Addition of Restorelle® Polypropylene Mesh and Altis® Single Incision Sling System	2499115	19 October 2022
13.0	Addition of Urine bags	2701701	25 October 2022

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	**Product Name**	**Class**
Silicone dressings Moist wound healing and exudate management	Biatain Silicone	IIb
Silicone dressings Moist wound healing and exudate management	Biatain Silicone Lite	IIb
Silicone dressings Moist wound healing and exudate management	Biatain Silicone Non-Border	IIb
Urinary Catheters	Sterile intermittent catheters	Is
Surgical instruments	Reusable surgical instruments	Ir
Urological stents Drainage of the upper urinary tract over fistulas or ureteral obstacles and healing of the ureter	Biosoft Duo	IIb*
Penile implants System surgically implanted for the management of erectile dysfunction	Titan	IIb*
Penile implant accessories To facilitate assembly and implant of the Titan IPP	Titan	IIb*
Drainage bags	Sterile drainage bags	Is
Endourological instrument	Steerable Pusher	IIa
Endourological instrument	Hybrid Guidewire	IIa

Foam dressing with silver	Biatain Ag Adhesive	III*
Foam dressing with silver	Biatain Ag Non-Adhesive	III*
Silicone foam dressing with silver	Biatain Silicone Ag	III*
Surgical Mesh	Restorelle® Polypropylene Mesh	III*
Single Incision Sling System	Altis® Single Incision Sling System	III*
Urine bags	Sterile urine collection bags	Is

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C536740, C545160 and C566662-NoMa-DNK

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Coloplast A/S	Holtedam 1-3, 3050 Humlebaek, Denmark
Coloplast Hungary KFT	Coloplast utca 2, 4300 Nyirbátor, Hungary
Coloplast Hungary KFT	Kerék utca 3, 2800 Tatabánya, Hungary
Coloplast (China) Ltd.	No. 202, Baocheng Rd, Xiangzhou District, Zhuhai 519030, China
Coloplast Corporation	1601 West River Road North, Minneapolis, MN 55411, USA
Coloplast Manufacturing US, LLC	1601 West River Road North, Minneapolis, MN 55411, USA
Coloplast Manufacturing France SAS	9 Avenue Edmond Rostand, CS 70218, 24206 Sarlat-la-Canéda Cedex, France
Coloplast Manufacturing France SAS	20 rue Blaise Pascal, 24200 Sarlat La Canéda, France
Coloplast Manufacturing France SAS	2b, Route du Chemin Blanc, ZAC du Clotais, 91160 Champlan, France
Coloplast Manufacturing France SAS	Lieudit La Boursidière, Centre d'Affaires, 92350 Le Plessis Robinson, France

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.