

EU Declaration of Conformity

Manufacturer Name: Ontex BV

Manufacturer Address: Genthof 5, 9255 Buggenhout, Belgium

SRN (Single Registration Number): BE-MF-000003544

Basic UDI-DI: 5414874LightIncoH6

Product Name: Incontinence products for light Inco – see attached list

Product Code: See attached list

Intended Purpose: The intended purpose of the light incontinence product family is to collect mild to moderate unintentional loss of urine or other body fluids, in order to keep the garments of the patient clean from said body fluids.
The devices are non-invasive, non-sterile, single-use disposable diapers, to be used in combination with underwear or a fixation pant.

Classification: Class I (according to Annex VIII of EU Regulation 2017/745 on medical devices) based on rule 1.

Conformity Assessment Route: EU Regulation 2017/745 on medical devices Annex II, III, IV and V

GMDN Code: 35817

CND Code: T040101

EMDN Code: T04010199 Light Inco Pad Flexfit & Traditional
T04010199 Light Inco Male pouch
T04010101 Rectangular

We hereby declare, under our own sole responsibility, that the medical device(s) specified above meet the provisions of the European Council Regulation 2017/745 for medical devices, and any other relevant EU legislation applicable to the device(s). All supporting documentation is retained at the premises of the manufacturer.

This declaration is signed on behalf of the manufacturer, Ontex BV, and is issued at the address of the manufacturer.


Chloe Vandeveld
PRRC

2025-04-02
Date (YYYY-MM-DD)

Ontex BV
Registered Office
Genthof 5
B-9255 Buggenhout

Headquarters Ontex BV, Korte Keppestraat 21, B-9320 Aalst (Lembodegem)
T +32(0)53 333 600 F +32(0)53 790 342 www.ontexglobal.com
RPR Dendermonde BTW BE0419.457.296 KBC IBAN BE 7310 1366 9796 BIC KREDBEBB

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Appendix Models

iD Discreet		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
IDD10101928	iD Discreet Light Pads Ultra mini 28pcs	I,1
IDD21052910	iD Discreet Light Pads Super 10pcs	I,1
IDD23062912	iD Discreet Light Pads Maxi Night 12pcs	I,1
IDD22060910	iD Discreet Light Pads Maxi 10pcs	I,1
IDD21051910	iD Discreet Light Pads Extra Plus 10pcs	I,1
IDD21041912	iD Discreet Light Pads Normal 12pcs	I,1
IDD21031916	iD Discreet Light Pads Mini Plus 16 pcs	I,1
IDD21021920	iD Discreet Light Pads Mini 20pcs	I,1
IDD31331914	iD Discreet Pads For men Super 14 pcs	I,1
IDD31221910	iD Discreet Pads For men Extra Plus 10pcs	I,1
IDD31111910	iD Discreet Pads For men Normal 10pcs	I,1

iD Essential		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
IDE20041928	iD Essential Light pads Normal 280 x 28	I, 1
IDE20051928	iD Essential Light pads Extra Plus 350 x 28	I, 1
IDE20061928	iD Essential Light pads Super 405 x 28	I, 1

iD Expert Light		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5160030280	iD Expert Light Normal	I,1
5160040280	iD Expert Light Extra	I,1
5160050280	iD Expert Light Maxi	I,1

iD Expert Rectangular (Spanish language)		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5936010200	ID EXPERT RECTANGULAR PAD	I, 1

iD For Men		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5221035100	iD For Men Level 1+	I,1
5221040100	iD For Men Level 2	I,1
5231050140	iD For Men Level 3	I,1

iD Light		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5111010281	iD Light Advanced Ultra Mini	I,1
5121020201	iD Light Advanced Mini	I,1
5171025161	iD Light Advanced Mini Plus	I,1
5171030121	iD Light Advanced Normal	I,1
5171040101	iD Light Advanced Extra	I,1
5171055101	iD Light Advanced Maxi	I,1
5171070100	iD Light Advanced Super	I,1

iD Rectangular		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5936010200	iD EXPERT Rectangular Día 80	I,1
59154700280	iD Rectangular Insert Extra	I,1
59154720280	iD Rectangular Pad Extra	I,1
59156000280	iD Rectangular Insert Maxi Plus	I,1
59156020280	iD Rectangular Pad Maxi Plus	I,1
59300820120	iD Rectangular Pad Normal	I,1
59361100280	iD Rectangular Insert Mini	I,1
59361120280	iD Rectangular Pad Mini	I,1
5910000501	iD Expert Rectangular Extra	I,1
5910020282	iD Expert Rectangular Extra	I,1
5920020280	iD Expert Rectangular Maxi	I,1
5930000280	iD Expert Rectangular Maxi	I,1
5930010280	iD Expert Rectangular Maxi+	I,1
59606500280	iD Anatomical Insert Straight Pads Normal	I,1
59606510280	iD Anatomical Pad with plastic backing Normal	I, 1
5900020120	iD Expert Rectangular Pad	I, 1

Lille Classic Pad		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
LCLN1111	Lille Classic Pad Mini	I, 1
LCLN1121	Lille Classic Pad Extra	I, 1
LCLN1131	Lille Classic Pad Maxi	I, 1
LCLN2111	Lille Classic Pad with plastic backing Mini	I, 1
LCLN2131	Lille Classic Pad with plastic backing Extra	I, 1
LCLN2151	Lille Classic Pad with plastic backing Maxi	I, 1

Lille Healthcare Suprem Light		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
LSFE3121	Lille Healthcare Suprem Light Mini	I,1
LSFE3131	Lille Healthcare Suprem Light Normal	I,1
LSFE3141	Lille Healthcare Suprem Light Extra	I,1
LSFE3145	Lille Healthcare Suprem Light Extra Plus	I,1
LSFE3151	Lille Healthcare Suprem Light Super	I,1
LSFE3161	Lille Healthcare Suprem Light Maxi	I,1
LSP22041928	Lille Healthcare Suprem Light Normal X28	I,1
LSP22051928	Lille Healthcare Suprem Light Extra X28	I,1
LSP22052916	Lille Healthcare Suprem Light Extra Plus X16	I,1
LSP22060928	Lille Healthcare Suprem Light pads Maxi x28	I,1
LSP23062930	Lille Healthcare Suprem Light pads Maxi Night X8	I,1
LSP20061930	Lille Healthcare Suprem Light pads Super X30	I,1

Lille Suprem For Men		
Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
LSFE3171	Lille Suprem forMen Extra	I,1
LSFE3181	Lille Suprem forMen Super	I,1