

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.

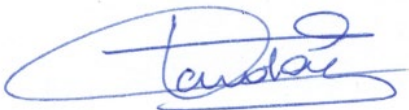
Conformity Assessment Route: EU Regulation 2017/745 on medical devices Annex II, III, IV and V

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.



2021-06-08

Katrien Cardoen
PRRC

Date

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Appendix
Models

iD Light

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

Rectangular

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5936010200	iD EXPERT Rectangular Día 80	I,1
59154700280	RECTANGULAR INSERT 47X15 NW 28	I,1
59154720280	RECTANGULAR PAD 47X15 PE+S 28	I,1
59156000280	RECTANGULAR INSERT 60X15 NW 28	I,1
59156020280	RECTANGULAR PAD 60X15 PE+S 28	I,1
59300820120	RECTANGULAR PAD 30,5X8 PE+S 12	I,1
59361100280	RECTANGULAR INSERT 36X11 NW 28	I,1
59361120280	RECTANGULAR PAD 36X11 PE+S 28	I,1
59606500280	ANATOMICAL INSERT NW 28	I,1
59606510280	ANATOMICAL PAD PE 28	I,1

Lille Suprem Light

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
LSFE3121	SUPREM LIGHT MINI (N2) 20	I,1
LSFE3131	SUPREM LIGHT NORMAL N4 28	I,1
LSFE3141	SUPREM LIGHT EXTRA N5 28	I,1

LSFE3145	SUPREM LIGHT EXTRA PLUS N5+ 16	I,1
LSFE3151	SUPREM LIGHT SUPER 28X10X24	I,1
LSFE3161	SUPREM LIGHT MAXI 28X10X20	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	SUPREM FOR MEN SUPER N 2 21	I,1

Light Inco

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
10109281	N6+ Einlage mit Klebestreifen	I,1
5160030011	N4 Einlage mit Klebestreifen 28	I,1
5160040010	N5 Einlage mit Klebestreifen	I,1
5160050010	N6 Einlage mit Klebestreifen 28	I,1