

## 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:** 5414874HeavyIncoG5

**Product Name:** Incontinence products for Heavy Incontinence – see list attached

**Product Code:** See attached list

**Intended Purpose:** The intended purpose of the Heavy Inco product family is to collect urine and/or faeces. The devices are non-invasive, non-sterile, single-use disposable diapers to be used independently or in combination with 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:** 41588 – Adults Pants, Junior Pants  
11239 – All-In-One Belt  
35817 – Shaped Pads

**CND Code:** T040101

**EMDN Code:** T04010103 – Adult Pants, Junior Pants, All-In-One, Belt  
T04010102 - Shaped Pads

**UK-REP name** Emergo Consulting (UK) Limited  
c/o Cr 360 – UL International

**UK-REP address** Compass House, Vision Park Histon  
Cambridge CB24 9BZ  
United Kingdom

**CH-REP name** MedEnvoy Switzerland

**CH-REP address** Gotthardstrasse 28  
6302 Zug  
Switzerland

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.



Bart Waterschoot  
PRRC

2023-02-06

Date (YYYY-MM-DD)

## EU Declaration of Conformity

### Appendix Models

#### iD Pants

Catalog/Reference/Product Number or code	Product name or description	Classification Rule
5531255140	iD Pants Normal Medium	I, 1
5531355140	iD Pants Normal Large	I, 1
5531065141	iD Pants Plus Extra Small	I, 1
5531165140	iD Pants Plus Small	I, 1
5531265140	iD Pants Plus Medium	I, 1
5531365140D	iD Pants Plus Large	I, 1
5531465140	iD Pants Plus Extra Large	I, 1
5531275120	iD Pants Super Medium	I, 1
5531375120D	iD Pants Super Large	I, 1
5531475120	iD Pants Super Extra Large	I, 1
5531280100	iD Pants Maxi Medium	I, 1
5531380100	iD Pants Maxi Large	I, 1
5531480100	iD Pants Maxi Extra Large	I, 1
5531275140	iD Pants Super M	I, 1
5531280140	iD Pants Maxi Medium	I, 1
5531375140	iD Pants Super Large	I, 1
5531380140	iD Pants Maxi Large	I, 1
6341047	iD Pants Plus Large	I, 1
5531575120	iD Pants Super XXL	I, 1
5531365146	iD Pants Plus Large	I, 1
6341046	iD Pants Plus Medium	I, 1
6341048	iD Pants Plus Extra Large	I, 1
5531365140	iD Pants Plus Large	I, 1
5521255120	iD Pants Fit&Feel Normal M	I, 1
5521265120	iD Pants Fit&Feel Plus M	I, 1
5521355100	iD Pants Fit&Feel Normal L	I, 1

#### iD Pants Soft Feel

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5531255149	iD Pants Soft Feel Normal Medium	I, 1
5531355149	iD Pants Soft Feel Normal Large	I, 1
5531265149	iD Pants Soft Feel Plus Medium	I, 1
5531365149	iD Pants Soft Feel Plus Large	I, 1
5531275149	iD Pants Soft Feel Super Medium	I, 1
5531375149	iD Pants Soft Feel Super Large	I, 1

#### iD Intime

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5551255120	iD Intime Normal Medium	I, 1
5551355100	iD Intime Normal Large	I, 1
5551265120	iD Intime Plus Medium	I, 1
5551365100	iD Intime Plus Large	I, 1

5551275120	iD Intime Super Medium	I, 1
5551375100	iD Intime Super Large	I, 1

#### iD For Men

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5521260120	iD For Men Level 4 Medium	I,1
5521360100	iD For Men Level 4 Large	I,1

#### iD Form

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5310155280	iD Form Normal Discreet	I, 1
5310260210	iD Form Plus Long	I, 1
5310265210	iD Form Extra Long	I, 1
5310270210	iD Form Extra Plus Long	I, 1
5310370210	iD Form Extra Plus Extra Long	I, 1
5310275210	iD Form Super Long	I, 1
5310375210	iD Form Super Extra Long	I, 1
5310380210	iD Form Maxi Extra Long	I, 1
5310260420UK	ID FORM TBS PLUS S2 N2 42	I, 1
5310265420UK	ID FORM TBS EXTRA S2 N3 42	I, 1
5310270420UK	ID FORM TBS EXTRA PLUS S2 N4 42	I,1
5310155286	ID Form	I, 1
5310260216-02	ID Form Pads	I, 1
5310265216-02	ID Form Fast Absorption	I, 1
5531165140-01	ID Pants Complete	I, 1

#### iD Care NP Net Pants

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5400100250	iD Care Net Pants Ultra Small	I, 1
5400200250	iD Care Net Pants Ultra Medium	I, 1
5400300250	iD Care Net Pants Ultra Large	I, 1
5400400250	iD Care Net Pants Ultra Extra Large	I, 1
5400500250	iD Care Net Pants Ultra Extra Extra Large	I, 1
5400600250	iD Care Net Pants Ultra Extra Extra Extra Large	I, 1
5410100050	iD Care Net Pants Comfort Super Small	I, 1
5410200050	iD Care Net Pants Comfort Super Medium	I, 1
5410200250	iD Care Net Pants Comfort Super Medium	I, 1
5410300050	iD Care Net Pants Comfort Super Large	I, 1
5410300250	iD Care Net Pants Comfort Super Large	I, 1
5410400050	iD Care Net Pants Comfort Super Extra Large	I, 1
5410400250	iD Care Net Pants Comfort Super Extra Large	I, 1
5410500050	iD Care Net Pants Comfort Super Extra Extra Large	I, 1

5410600030	iD Care Net Pants Comfort Super Extra Extra Extra Large	I, 1
5420100050	iD Care Net Pants With Legs Small	I, 1
5420200050	iD Care Net Pants With Legs Medium	I, 1
5420300050	iD Care Net Pants With Legs Large	I, 1
5420400050	iD Care Net Pants With Legs Extra Large	I, 1
5420500050	iD Care Net Pants With Legs Extra Extra Large	I, 1
5420600050	iD Care Net Pants With Legs Extra Extra Extra Large	I, 1
5420150050	iD Care Net Pants With Legs S/M x5 50-90cm	I, 1
5420550050	iD Care Net Pants With Legs 2XL/3XL x5 115cm-165cm	I, 1

### iD Slip

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5630160140	iD Slip Plus Small	I, 1
5630260150	iD Slip Plus Medium	I, 1
5610260280	iD Slip Plus Medium	I, 1
5630360150	iD Slip Plus Large	I, 1
5610360280	iD Slip Plus Large	I, 1
5630460140	iD Slip Plus X-Large	I, 1
5630165140	iD Slip Extra Small	I, 1
5610265280	iD Slip Extra Medium	I, 1
5610365280	iD Slip Extra Large	I, 1
5630465140	iD Slip Extra X-Large	I, 1
5610270280	iD Slip Extra Plus Medium	I, 1
5610370280	iD Slip Extra Plus Large	I, 1
5630075140	iD Slip Super X-Small	I, 1
5630175140	iD Slip Super Small	I, 1
5630275150	iD Slip Super Medium	I, 1
5630275280	iD Slip Super Medium	I, 1
5630375150	iD Slip Super Large	I, 1
5630375280	iD Slip Super Large	I, 1
5630475140	iD Slip Super X-Large	I, 1
5630180200	iD Slip Maxi Small	I, 1
5630280151	iD Slip Maxi Medium	I, 1
5630380151	iD Slip Maxi Large	I, 1
5630480150	iD Slip Maxi X-Large	I, 1
56302100150	iD Slip Maxi Prime Medium	I, 1
56303100150	iD Slip Maxi Prime Large	I, 1
5631275200	iD Slip Super M	I, 1
5631375200	iD Slip TBS Super L N4 20	I, 1
5630170140	ID Slip Extra Plus S	I, 1
5630470140	ID Slip Extra Plus XL	I, 1
5630575150	iD Slip Super XXL Bariatric	I, 1

### iD Expert Slip PE

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
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5600255280	iD Expert Slip Normal Medium	I, 1
5600355280	iD Expert Slip Normal Large	I, 1
5600260280	iD Expert Slip Plus Medium	I, 1
5600360280	iD Expert Slip Plus Large	I, 1
5600270280	iD Expert Slip Extra Plus Medium	I, 1
5600370280	iD Expert Slip Extra Plus Large	I, 1
5620275280	iD Expert Slip Super Medium	I, 1
5620375280	iD Expert Slip Super Large	I, 1
5630375301	iD Expert Slip Super Large	I, 1
5630275301	iD Expert Slip Super Medium	I, 1
5600260300	iD Expert Slip Plus M	I, 1
5600270300	iD Expert Slip Extra Plus M	I, 1
5600360300	iD Expert Slip Plus L	I, 1
5600370300	iD Expert Slip Extra Plus L	I, 1

#### MePro iD Expert Slip

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5610365300	iD EXPERT Slip Extra Large	I, 1

#### Orizon by iD Slip

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5640260280	Orizon by iD Smart Slip Plus Medium	I, 1
5640360280	Orizon by iD Smart Slip Plus Large	I, 1
5640270280	Orizon by iD Smart Slip Extra Plus Medium	I, 1
5640370280	Orizon by iD Smart Slip Extra Plus Large	I, 1
5640275280	Orizon by iD Smart Slip Super Medium	I, 1
5640375280	Orizon by iD Smart Slip Super Large	I, 1

#### Orizon by Serenity Slip

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
40573280000	Orizon by Serenity Smart Slip Extra Large	I, 1
40572280000	Orizon by Serenity Smart Slip Extra Medium	I, 1
40583280000	Orizon by Serenity Smart Slip Super Large	I, 1
40582280000	Orizon by Serenity Smart Slip Super Medium	I, 1
40593280000	Orizon by Serenity Smart Slip Maxi Large	I, 1
40592280000	Orizon by Serenity Smart Slip Maxi Medium	I, 1

#### Orizon by Serenity Shaped

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
40917210000	Orizon by Serenity Smart Form Super Large	I, 1
40918210000	Orizon by Serenity Smart Form Super Extra Large	I, 1
40919210000	Orizon by Serenity Smart Form Maxi Extra Large	I, 1

#### ID Belt

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
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5700160140	iD Belt Plus Small	I, 1
5700260140	iD Belt Plus Medium	I, 1
5700360140	iD Belt Plus Large	I, 1
5700460140	iD Belt Plus Extra Large	I, 1
5700175140	iD Belt Super Small	I, 1
5700275140	iD Belt Super Medium	I, 1
5700375140	iD Belt Super Large	I, 1
5700475140	iD Belt Super Extra Large	I, 1
5700180140	iD Belt Maxi Small	I, 1
5700280140	iD Belt Maxi Medium	I, 1
5700380140	iD Belt Maxi Large	I, 1
5700480140	iD Belt Maxi Extra Large	I, 1
5700285140	iD Belt Maxi Plus Medium	I, 1
5700385140	iD Belt Maxi Plus Large	I, 1

#### iD Innofit

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5712260140	iD Innofit Plus Medium	I, 1
5712360140	iD Innofit Plus Large	I, 1
5712270140	iD Innofit Extra Plus Medium	I, 1
5712370140	iD Innofit Extra Plus Large	I, 1
5712280140	iD Innofit Maxi Medium	I, 1
5712380140	iD Innofit Maxi Large	I, 1

#### iD Comfy Junior

Catalog/Reference/Product Number or code	Product name or description	Classification Rule
5501135140	iD Comfy Junior Pants 4-7 years	I, 1
5501245140	iD Comfy Junior Pants 8-15 year	I, 1
5501025140	iD Comfy Junior XS Slip	I, 1

#### Orizon by iD Form

Catalog/Reference/Product Number or code	Product name or description	Classification Rule
5340260420	Orizon by iD Smart Form Plus L2	I, 1
5340270420	Orizon by iD Smart Form Extra Plus L4	I, 1
5340370210	Orizon by iD Smart Form Extra Plus XL5	I, 1
5340275210	Orizon by iD Smart Form Super L5	I, 1
5340375210	Orizon by iD Smart Form Super XL6	I, 1

#### Lille Suprem Pants

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSPU0311PO	Suprem Pants Large Extra	I, 1
LSPU0321PO	Suprem Pants Large Maxi	I, 1
LSPU0211PO	Suprem Pants Medium Extra	I, 1
LSPU0221PO	Suprem Pants Medium Maxi	I, 1
LSPU0311	Suprem Pants Large Extra	I, 1
LSPU0321	Suprem Pants Large Maxi	I, 1
LSPU0315	Suprem Pants Large Super	I, 1
LSPU0211	Suprem Pants Medium Extra	I, 1
LSPU0221	Suprem Pants Medium Maxi	I, 1

LSPU0121	Suprem Pants Small Maxi	I, 1
LSPU0411	Suprem Pants XLarge Extra	I, 1
LSPU0421	Suprem Pants XLarge Maxi	I, 1
LSPU0415	Suprem Pants XLarge Super	I, 1

#### Lille Suprem Form

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSFM5111BR	Suprem Form Regular	I, 1
LSFM5121BR	Suprem Form Regular Plus	I, 1
LSFM5141BR	Suprem Form Extra Plus	I, 1
LSFM5161BR	Suprem Form Super Plus	I, 1
LSFM5171BR	Suprem Form Maxi	I, 1

#### Lille Classic Form

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LCFM4111	Classic Form Shaped Pads Regular	I, 1
LCFM4121	Classic Form Shaped Pads Extra	I, 1
LCFM4131	Classic Form Shaped Pads Super	I, 1

#### Lille Suprem Fit

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSFT7341PO	Suprem Fit Large Maxi	I, 1
LSFT7241PO	Suprem Fit Medium Maxi	I, 1
LSFT7311BR	Suprem Fit Large Regular Plus	I, 1
LSFT7321BR	Suprem Fit Large Extra Plus	I, 1
LSFT7341BR	Suprem Fit Large Maxi	I, 1
LSFT7331BR	Suprem Fit Large Super Plus	I, 1
LSFT7321PO	Suprem Fit Large Extra+	I, 1
LSFT7331PO	Suprem Fit Large Super+	I, 1
LSFT7221BR	Suprem Fit Medium Extra Plus	I, 1
LSFT7241BR	Suprem Fit Medium Maxi	I, 1
LSFT7211BR	Suprem Fit Medium Regular Plus	I, 1
LSFT7231BR	Suprem Fit Medium Super Plus	I, 1
LSFT7221PO	Suprem Fit Medium Extra Plus	I, 1
LSFT7231PO	Suprem Fit Medium Super Plus	I, 1
LSFT7111BR	Suprem Fit Small Extra Plus	I, 1
LSFT7121BR	Suprem Fit Small Maxi	I, 1
LSFT7411BR	Suprem Fit XLarge Extra Plus	I, 1
LSFT7421BR	Suprem Fit XLarge Maxi	I, 1
LSFT7211PO	Suprem Fit Regular Plus Medium	I, 1
LSFT7311PO	Suprem Fit Regular Plus Large	I, 1

#### Lille Classic Fit (Spanish language)

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
CLCFT6211SP	CLASSIC FIT Mediana Noche 80	I, 1
CLCFT6311SP	CLASSIC FIT Grande Noche 80	I, 1
CLCFT6321SP	CLASSIC FIT Grande Super noche 80	I, 1
LCFT6421SP	CLASSIC FIT Extra Grande Super noche 60	I, 1

**iD Expert Form (Spanish language)**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
5306060200	iD EXPERT Form Día	I, 1
5306070200	iD EXPERT Form Noche	I, 1
5306075200	iD EXPERT Form Super Noche	I, 1

**iD Expert Slip (Spanish language)**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
5626360200	iD EXPERT Slip Grande Día	I, 1
5626370200	iD EXPERT Slip Grande Noche	I, 1
5626375200	iD EXPERT Slip Grande Super Noche	I, 1
5626270200	iD EXPERT Slip Mediana Noche	I, 1
5626275200	iD EXPERT Slip Mediana Super Noche	I, 1

**iD Consumer**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
747341920	iD Slip Extra Plus L	I, 1
747241920	iD Slip Extra Plus M	I, 1
747311920	iD Slip Plus L	I, 1
747211920	iD Slip Plus M	I, 1
730211920	iD Pants Plus M	I, 1
730311920	iD Pants Plus L	I, 1