

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.

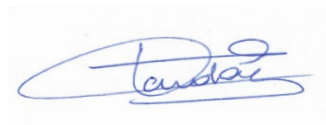
Conformity Assessment Route: EU Regulation 2017/745 on medical devices Annex II, III, IV and V

CND Code: T040101

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

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.



Katrien Cardoen
PRRC

2021-06-08
Date (YYYY-MM-DD)

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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 X-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 X-Large	I, 1
5531275120	iD Pants Super Medium	I, 1
5531375120D	iD Pants Super Large	I, 1
5531475120	iD Pants Super X-Large	I, 1
5531280100	iD Pants Maxi Medium	I, 1
5531380100	iD Pants Maxi Large	I, 1
5531480100	iD Pants Maxi XL	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 Form

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5310155280	iD Form Normal Size 1	I, 1
5310260210	iD Form Plus Size 2	I, 1
5310265210	iD Form Extra Size 2	I, 1
5310270210	iD Form Extra Plus Size 2	I, 1
5310370210	iD Form Extra Plus Size 3	I, 1

5310275210	iD Form Super Size 2	I, 1
5310375210	iD Form Super Size 3	I, 1
5310380210	iD Form Maxi Size 3	I, 1

iD Care NP Net Pants

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5400100250	iD Care NP Ultra Small	I, 1
5400200250	iD Care NP Ultra Medium	I, 1
5400300250	iD Care NP Ultra Large	I, 1
5400400250	iD Care NP Ultra X-Large	I, 1
5400500250	iD Care NP Ultra XX-Large	I, 1
5400600250	iD Care NP Ultra XXX-Large	I, 1
5410100050	iD Care NP Comfort Small	I, 1
5410200050	iD Care NP Comfort Medium	I, 1
5410200250	iD Care NP Comfort Medium	I, 1
5410300050	iD Care NP Comfort Large	I, 1
5410300250	iD Care NP Comfort Large	I, 1
5410400050	iD Care NP Comfort X-Large	I, 1
5410400250	iD Care NP Comfort X-Large	I, 1
5410500050	iD Care NP Comfort XX-Large	I, 1
5410600030	iD Care NP Comfort XXX-Large	I, 1
5420100050	iD Care NP Panty Small	I, 1
5420200050	iD Care NP Panty Medium	I, 1
5420300050	iD Care NP Panty Large	I, 1
5420400050	iD Care NP Panty X-Large	I, 1
5420500050	iD Care NP Panty XX-Large	I, 1
5420600050	iD Care NP Panty XXX-Large	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

iD Expert Slip PE

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5600255280	iD Expert Slip PE Normal Medium	I, 1
5600355280	iD Expert Slip PE Normal Large	I, 1
5600260280	iD Expert Slip PE Plus Medium	I, 1
5600360280	iD Expert Slip PE Plus Large	I, 1
5600270280	iD Expert Slip PE Extra Plus Medium	I, 1
5600370280	iD Expert Slip PE Extra Plus Large	I, 1
5620275280	iD Expert Slip PE Super Medium	I, 1
5620375280	iD Expert Slip PE Super Large	I, 1

iD Belt

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
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 X-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 X-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 X-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 Slip X-Small	I, 1

Lille Suprem Pants

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSPU0311PO	COUCHE ADULTE LIL L EXTRA 14X8	I, 1
LSPU0321PO	LILLE PANTS L N3 15	I, 1
LSPU0211PO	LILLE PANTS M N1 15	I, 1
LSPU0221PO	LILLE PANTS M N3 15	I, 1
LSPU0311	SUPREM PANTS L EXTRA N1 14	I, 1
LSPU0321	SUPREM PANTS L MAXI N3 14	I, 1
LSPU0315	SUPREM PANTS L SUPER N3 14	I, 1
LSPU0211	SUPREM PANTS M EXTRA N1 14	I, 1
LSPU0221	SUPREM PANTS M MAXI - CAROLINE	I, 1
LSPU0121	SUPREM PANTS S MAXI 14	I, 1
LSPU0411	SUPREM PANTS XL EXTRA N1 14	I, 1
LSPU0421	SUPREM PANTS XL MAXI - CAROLINE	I, 1
LSPU0415	SUPREM PANTS XL SUPER N3 14	I, 1

Lille Suprem Form

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSFM5111BR	SUPREM FORM REGULAR N4 25	I, 1
LSFM5121BR	SUPREM FORM REGULAR +25	I, 1
LSFM5141BR	SUPREM FORM EXTRA + 25	I, 1
LSFM5161BR	SUPREM FORM SUPER + 20	I, 1
LSFM5171BR	SUPREM FORM MAXI 20	I, 1

Lille Classic Form

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LCFM4111	LILLE CLASSIC FORM REGULAR	I, 1
LCFM4121	LILLE CLASSIC FORM EXTRA	I, 1
LCFM4131	LILLE CLASSIC FORM SUPER	I, 1

Lille Suprem Fit

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
LSFT7341PO	LILLE SUPREMFIT MAXI L	I, 1
LSFT7241PO	LILLE SUPREMFIT MAXI M	I, 1
LSFT7311BR	SUPREM FIL L REGULAR+ 26	I, 1
LSFT7321BR	SUPREM FIT L EXTRA+ 24	I, 1
LSFT7341BR	SUPREM FIT L MAXI 20	I, 1

LSFT7331BR	SUPREM FIT L SUPER+ 22	I, 1
LSFT7321PO	SUPREM FIT LARGE EXTRA+	I, 1
LSFT7331PO	SUPREM FIT LARGE SUPER	I, 1
LSFT7221BR	SUPREM FIT M EXTRA+ 24	I, 1
LSFT7241BR	SUPREM FIT M MAXI 20	I, 1
LSFT7211BR	SUPREM FIT M REGULAR+ 26	I, 1
LSFT7231BR	SUPREM FIT M SUPER+ 22	I, 1
LSFT7221PO	SUPREM FIT MEDIUM EXTRA+	I, 1
LSFT7231PO	SUPREM FIT MEDIUM SUPER	I, 1
LSFT7111BR	SUPREM FIT S EXTRA+ 20	I, 1
LSFT7121BR	SUPREM FIT S MAXI 20	I, 1
LSFT7411BR	SUPREM FIT XL EXTRA+ 20	I, 1
LSFT7421BR	SUPREM FIT XL MAXI N4 20	I, 1

Catalog/Reference/ Product Number or code	Product name or description	Classification, Rule
130221402-01	Adult Pants Medium Extra	I,1
130321401	Adult Pants Large Extra	I,1
130421401	Adult Pants XL Extra	I,1