

ONTEX POLSKA Sp. z o.o.
ul. Przedsiębiorców 6
97-500 Radomsko
NIP 731-10-06-907, Regon 471116947

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.



2023-02-06

Bart Waterschoot
PRRC

Date (YYYY-MM-DD)

Ontex BV
Registered Office
Genthof 5
B-9255 Buggenhout

Headquarters Ontex BV, Korte Keppestraat 21, B-9320 Aalst (Erembodegem)
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

WE ARE TOGETHER

Ontex

EU Declaration of Conformity

Appendix Models

ONTEX POLSKA Sp. z o.o.
ul. Przedsiębiorców 6
97-500 Radomsko
NIP 731-10-06-907, Regon 471116947

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 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 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

ONTEX POLSKA Sp. z o.o.

ul. Przedsiębiorców 6

97-500 Radomsko

NIP 731-10-06-907, Regon 471116947

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