

## 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.

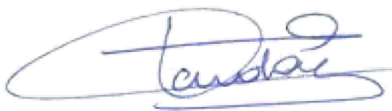
**Conformity Assessment Route:** EU Regulation 2017/745 on medical devices Annex II, III, IV and V

**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  
VP Quality - PRRC

Date 2021-05-18

## 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 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
5531275140W	iD Pants Super Medium	I , 1
5531275120	iD Pants Super Medium	I , 1
5531375140W	iD Pants Super Large	I , 1
5531375120D	ID Pants Super Large	I , 1
5531475140US	iD Pants Super X-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

#### 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 Pants Fit&Feel

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
5521255120	iD Pants Fit&Feel Normal Medium	I , 1
5521355100	iD Pants Fit&Feel Normal Large	I , 1
5521265120	iD Pants Fit&Feel Plus Medium	I , 1
5521365100	iD Pants Fit&Feel Plus Large	I , 1
5521275120	iD Pants Fit&Feel Super Medium	I , 1
5551375100	iD Pants Fit&Feel Super Large	I , 1

**iD Intime**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
5551255120	iD Intime Normal Medium	l , 1
5551355100	iD Intime Normal Large	l , 1
5551265120	iD Intime Plus Medium	l , 1
5551365100	iD Intime Plus Large	l , 1
5551275120	iD Intime Super Medium	l , 1
5551375100	iD Intime Super Large	l , 1

**iD Slip**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
5630160140	iD Slip Plus Small	l , 1
5630260150	iD Slip Plus Medium	l , 1
5610260280	iD Slip Plus Medium	l , 1
5630360150	iD Slip Plus Large	l , 1
5610360280	iD Slip Plus Large	l , 1
5630460140	iD Slip Plus X-Large	l , 1
5630165140	iD Slip Extra Small	l , 1
5610265280	iD Slip Extra Medium	l , 1
5610365280	iD Slip Extra Large	l , 1
5630465140	iD Slip Extra X-Large	l , 1
5610270280	iD Slip Extra Plus Medium	l , 1
5610370280	iD Slip Extra Plus Large	l , 1
5630075140	iD Slip Super X-Small	l , 1
5630175140	iD Slip Super Small	l , 1
5630275150	iD Slip Super Medium	l , 1
5630275280	iD Slip Super Medium	l , 1
5630375150	iD Slip Super Large	l , 1
5630375280	iD Slip Super Large	l , 1
5630475140	iD Slip Super X-Large	l , 1
5630180200	iD Slip Maxi Small	l , 1
5630280151	iD Slip Maxi Medium	l , 1
5630380151	iD Slip Maxi Large	l , 1
5630480150	iD Slip Maxi X-Large	l , 1
56302100150	iD Slip Maxi Prime Medium	l , 1
56303100150	iD Slip Maxi Prime Large	l , 1

**iD Expert Slip Intense**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
IDSOF27515	iD Expert Slip Intense Super Medium	l , 1
IDSOF28015	iD Expert Slip Intense Maxi Medium	l , 1
IDSOF37515	iD Expert Slip Intense Super Large	l , 1

**iD Expert Slip PE**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
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
5600275280	iD Expert Slip PE Super Medium	I , 1
5600375280	iD Expert Slip PE Super Large	I , 1

#### **iD Belt**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
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**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name and description</b>	<b>Classification Rule</b>
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**

<b>Catalog/Reference/Product Number or code</b>	<b>Product name or description</b>	<b>Classification Rule</b>
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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

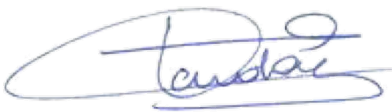
## EU Declaration of Conformity

**Manufacturer Name:** Ontex BV  
**Manufacturer Address:** Genthof 5, 9255 Buggenhout, Belgium  
**SRN (Single Registration Number):** BE-MF-000003544  
**Basic UDI-DI:** 5414874UnderpadsUU  
**Product Name:** Underpads  
**Product Code:** See attached list  
**Intended Purpose:** The intended purpose of the Underpads is to be placed on a surface and/or underneath a patient to absorb urine and or faeces, as a protection sheet. The devices are non-invasive, non-sterile, single-use products to be used independently or in combination with other incontinence products.

**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:** T040102  
**EMDN Code:** T04010201 Untackable underpad  
T04010202 Tackable underpad

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Katrien Cardoen  
VP Quality

Date 2021-05-18

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### Appendix Models

#### iD Expert Protect

Catalog/Reference/Product Number	Product name and description	Classification, Rule
5800460300	iD Expert Protect Plus 40x60	I, 1
5800475300	iD Expert Protect Super 40x60	I, 1
5800660300	iD Expert Protect Plus 60x60	I, 1
5800675300	iD Expert Protect Super 60x60	I, 1
5800775300	iD Expert Protect Super 60x75	I, 1
5800960300	iD Expert Protect Plus 60x90	I, 1
5800975300	iD Expert Protect Super 60x90	I, 1
5800075200	iD Expert Protect Super 90x180	I, 1
5800975100	iD Expert Protect Super 60x90	I, 1

## 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.

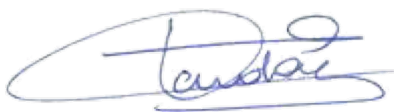
**Conformity Assessment Route:** EU Regulation 2017/745 on medical devices Annex II, III, IV and V

**CND Code:** T040101

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

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Date 2021-18-05



## EU Declaration of Conformity

### 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

#### 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 Expert Rectangular

Catalog/Reference/Product Number or code	Product name or description	Classification, Rule
5900000120	iD Expert Rectangular Normal 80x305 NW	I,1
5900020120	iD Expert Rectangular Normal 80x305 PE + strip	I,1
5910000501	iD Expert Rectangular Extra 110x360 NW	I,1
5910020282	iD Expert Rectangular Extra 110x360 PE + strip	I,1
5920020280	iD Expert Rectangular Maxi 150x470 PE + strip	I,1
5930000280	iD Expert Rectangular Maxi 150x600 NW	I,1
5930010280	iD Expert Rectangular Maxi 150x600 PE	I,1
5940000280	iD Expert Rectangular Anatomical Insert NW	I,1
5940010280	iD Expert Rectangular Anatomical Insert PE	I,1