

## 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.

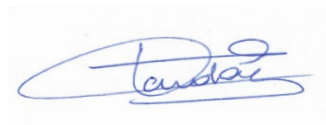
**Conformity Assessment Route:** EU Regulation 2017/745 on medical devices Annex II, III, IV and V

**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)

## 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                |
| 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**

| <b>Catalog/Reference/Product Number or code</b> | <b>Product name or description</b> | <b>Classification, Rule</b> |
|---|------------------------------------|-----------------------------|
| 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**

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

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

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

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

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

**Lille Suprem Fit**

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

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