

## 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

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.



2021-05-19

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Katrien Cardoen  
VP Quality

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Date (YYYY-MM-DD)

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### Appendix Models

#### iD Expert Protect

Catalog/Reference/Product Number or code	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

#### iD Protect

Catalog/Reference/Product Number or code	Product name and description	Classification, Rule
5801660300	iD Protect Plus 60x60	I, 1
5801675300	iD Protect Super 60x60	I, 1
5801960300	iD Protect Plus 60x90	I, 1
5801975300	iD Protect Super 60x90	I, 1

#### Lille ClassicBed

Catalog/Reference/Product Number or code	Product name and description	Classification, Rule
LFBD8111	Lille ClassicBed Extra 40x60	I, 1
LFBD8211	Lille ClassicBed Extra 60x60	I, 1
LFBD8221	Lille ClassicBed Super 60x60	I, 1
LFBD8311	Lille ClassicBed Extra 60x75	I, 1
LFBD8401	Lille ClassicBed Basic 60x90	I, 1
LFBD8411	Lille ClassicBed Extra 60x90	I, 1
LFBD8411MM	Lille ClassicBed Extra 60x90 25x2x52	I, 1
LFBD8415	Lille ClassicBed Super 60x90	I, 1
LFBD8421	Lille ClassicBed Maxi 60x90	I, 1
LFBD8511	Lille ClassicBed Extra 90x180	I, 1