

EU DECLARATION OF CONFORMITY

Essity Hygiene and Health AB
SE-405 03 Göteborg
Sweden
Visitor's address: Mölndals Bro 2, Mölndal

SRN number: SE-MF-000000004

hereby declares being the manufacturer* of the medical devices TENA Comfort according to the enclosed article number list, and that the devices are in conformity with Medical Device Regulation (EU) 2017/745 (MDR) and fulfil all relevant requirements in MDR.

The devices are intended for incontinence care and are classified in Class I according to Annex VIII in MDR.

The GMDN code is 11239, the EMDN/CND code is T04010102 and the Basic UDI-DI is 7322540100736V.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Mölndal, on January 2021-01-26



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Romana Stefek
Global Regulatory Affairs/Product Safety Director
LM Essity Hygiene and Health AB

* per definition in Medical Device Regulation (EU) 2017/745

This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB
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Visitors' address: Mölndals Bro 2, Mölndal
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| Document Name | Document ID | Version |
|---------------------------|-------------|---------|
| Declaration of Conformity | FORM-00733 | 4.0 |

| Article Number | Article | UDI-DI |
|----------------|--------------------------------------------------|---------------|
| 100174 | TENA Comfort Normal Ps 104x1pcs AB | 7322541248219 |
| 100175 | TENA Comfort Plus Ps 52x1pcs AB | 7322541248288 |
| 100192 | TENA Comfort Extra Ps 52x1pcs AB | 7322541250182 |
| 100193 | TENA Comfort Super Ps 52x1pcs AB | 7322541250250 |
| 100194 | TENA Comfort Maxi Ps 36x1pcs AB | 7322541250328 |
| 100195 | TENA Comfort Original Normal 104x1p AB | 7322541250618 |
| 100196 | TENA Comfort Original Plus 52x1pcs AB | 7322541250700 |
| 100197 | TENA Comfort Original Extra 52x1pcs AB | 7322541250786 |
| 100198 | TENA Comfort Ultima Ps 36x1pcs AB | 7322541250854 |
| 100199 | TENA Comfort Original Super 52x1pcs AB | 7322541250939 |
| 100201 | TENA Comfort Original Maxi 36x1pcs AB | 7322541251011 |
| 100202 | TENA Comfort Anatomico N 104x1pcs ES | 7322541251097 |
| 100203 | TENA Comfort Anatomico P 52x1pcs ES | 7322541251172 |
| 100204 | TENA Comfort Anatomico E 52x1pcs ES | 7322541251257 |
| 100205 | TENA Comfort Anatomico S 52x1pcs ES | 7322541251349 |
| 100501 | TENA Comfort Ultima Vinda Ps 48x1p AB | 7322541328881 |
| 211422 | TENA Comfort Original Value Norm 3x42p N | 7322540728682 |
| 211431 | TENA Comfort Original Value Plus 2x46p N | 7322541398785 |
| 211432 | TENA Comfort Original ValueExtra 2x40p N | 7322541398808 |
| 211433 | TENA Comfort Original Value Super 2x36 N | 7322541398921 |
| 211435 | TENA Comfort Original Value Maxi 2x28, N | 7322541398945 |
| 211436 | TENA Comfort Basic Value Plus 3x36 pcs | 7322541398969 |
| 211437 | TENA Comfort Basic Value Extra 3x36pcs | 7322541398983 |
| 211438 | TENA Comfort Basic Value Super 3x36pcs | 7322541399003 |
| 211439 | TENA Comfort Basic Value Maxi 3x28pcs | 7322541399027 |
| 211441 | TENA Comfort Basic Value Normal 3x36p | 7322541399041 |
| 211471 | TENA Comfort Original Normal 3x42 pcs,Neutral | 7322540710502 |
| 211472 | TENA Comfort Original Plus 2x40 pcs, Neutral | 7322540734515 |
| 211473 | TENA Comfort Original Extra 2x40 pcs, Neutral | 7322540710717 |
| 211474 | TENA Comfort Original Super 2x36 pcs, Neutral | 7322540710731 |

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|--------|-------------------------------------------------|---------------|
| 211475 | TENA Comfort Original Maxi 2x28 pcs, Neutral | 7322540710755 |
| 211476 | TENA Comfort Original Plus 2x46 pcs, Neutral | 7322540710694 |
| 212240 | TENA Anatomico Comfort Normal 3x40pcs ES | 7322540710649 |
| 212244 | TENA Comfort Anatomico Normal 2x40 p + Fix pant | 7322540834475 |
| 212742 | TENA Comfort Original Normal 3x42 pcs INT | 7322540710502 |
| 212840 | TENA Anatomico Comfort Plus 2x40 pcs ES | 7322540710779 |
| 212841 | TENA Comfort Anatomico Plus 2x40 p + Fix pant | 7322540835137 |
| 212846 | TENA Comfort Original Plus 2x46 pcs INT | 7322540710694 |
| 212850 | TENA Comfort Original Plus 2x40 pcs IT | 7322540734515 |
| 212940 | TENA Comfort Original Extra 2x40 pcs INT | 7322540710717 |
| 213040 | TENA Anatomico Comfort Extra 2x40 pcs ES | 7322540710793 |
| 213041 | TENA Comfort Anatomico Extra 2x40 p + Fix pant | 7322540835144 |
| 218036 | TENA Comfort Original Super 2x36 pcs INT | 7322540710731 |
| 218540 | TENA Anatomico Comfort Super 2x40 pcs ES | 7322540710816 |
| 218541 | TENA Comfort Anatomico Super 2x40 p + Fix pant | 7322540835151 |
| 219028 | TENA Comfort Original Maxi 2x28 pcs INT | 7322540710755 |
| 752742 | TENA Comfort Normal 3x42 pcs INT | 7322540696011 |
| 752846 | TENA Comfort Plus 2x46 pcs INT | 7322540696035 |
| 752859 | TENA Comfort Plus 20x40 pcs IT | 7322540736892 |
| 753040 | TENA Comfort Extra 2x40 pcs INT | 7322540696196 |
| 758037 | TENA Comfort super ES | 7322540414592 |
| 758136 | TENA Comfort Super 2x36 pcs INT | 7322540698107 |
| 759000 | TENA Comfort Normal, 3x42pcs, Neutral | 7322540696011 |
| 759002 | TENA Comfort Extra, 2x40p, Neutral | 7322540696196 |
| 759003 | TENA Comfort Super, 2x36pcs, Neutral | 7322540698107 |
| 759004 | TENA Comfort Maxi, 2x28pcs, Neutral | 7322540696219 |
| 759005 | TENA Comfort Plus, 2x46 pcs, Neutral | 7322540696035 |
| 759006 | TENA Comfort Ultima, 2x26pcs, Neutral | 7322541274201 |
| 759128 | TENA Comfort Maxi 2x28 pcs INT | 7322540696219 |

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ES PROHLÁŠENÍ O SHODĚ

Společnost

Essity Hygiene and Health AB

SE-405 03 Göteborg

Švédsko

Adresa pro návštěvy: Mölndals Bro 2, Mölndal

Číslo SRN: SE-MF-000000004

tímto prohlašuje, že je výrobcem* zdravotnických prostředků TENA Comfort Inkontinenční plena dle přiloženého seznamu a že tyto prostředky jsou v souladu s nařízením EU č. 2017/745 o zdravotnických prostředcích („nařízení“) a splňují všechny jeho příslušné požadavky.

Prostředky jsou určeny k péči o inkontinentní osoby a jsou klasifikovány jako třída I podle přílohy VIII nařízení.

GMDN kód je 11239, EMDN/CND kód je T04010102 a základní UDI-DI je 7322540100736V.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

Mölndal, 26. ledna 2021

[podpis]

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Romana Stefek

Ředitelka pro globální regulatorní problematiku a bezpečnost výrobků
LM Essity Hygiene and Health AB

**podle definice v nařízení (EU) č. 2017/745 o zdravotnických prostředcích*

Toto prohlášení zůstává v platnosti do vydání nové verze.

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Švédsko

Sídlo: Göteborgs kommun. Reg. číslo: SE556007-2356

Adresa pro návštěvy:
Mölndals Bro 2, Mölndal
Tel.: +46 31 746 00 00
www.essity.com

| Název dokumentu | ID dokumentu | Verze |
|--------------------|----------------|-------|
| Prohlášení o shodě | FORMULÁŘ 00733 | 4.0 |

| Č. položky | Položka | UDI-DI |
|------------|---------------------------------------------------|---------------|
| 100174 | TENA Comfort Normal Ps 104x1pcs AB | 7322541248219 |
| 100175 | TENA Comfort Plus Ps 52x1pcs AB | 7322541248288 |
| 100192 | TENA Comfort Extra Ps 52x1pcs AB | 7322541250182 |
| 100193 | TENA Comfort Super Ps 52x1pcs AB | 7322541250250 |
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| 211437 | TENA Comfort Basic Value Extra 3x36pcs | 7322541398983 |
| 211438 | TENA Comfort Basic Value Super 3x36pcs | 7322541399003 |
| 211439 | TENA Comfort Basic Value Maxi 3x28pcs | 7322541399027 |
| 211441 | TENA Comfort Basic Value Normal 3x36p | 7322541399041 |
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