# EU DECLARATION OF CONFORMITY

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|---|---|
| **Company:** | Essity Hygiene and Health AB<br>SE-405 03 Göteborg<br>Sweden<br>Visitor's address: Mölndals Bro 2, Mölndal, Sweden<br><br>SRN number: SE-MF-000000004 |
| **Product assortment:** | TENA Comfort |
| **Basic UDI-DI:** | 7322540100736V |
| **Medical devices:** | See enclosed list |
| **Risk class:** | Class I |
| **Common Specification:** | N/A |
| **Notified Body:** | N/A, since Class I device |
| **Declaration:** | We hereby declare being the manufacturer* of the medical devices 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 safety and functional requirements in MDR.<br><br>The devices are classified in according to Annex VIII in MDR. This Declaration of Conformity is issued under the sole responsibility of the manufacturer. |
| **Intended use:** | The devices are intended for incontinence care |
| **GMDN code:** | 11239 |
| **EMDN code:** | T04010102 |

**Signatory:** Mölndal, on 2023-07-03

Romana Stefek
Global Regulatory Affairs Director
PRRC Medical Devices, Cosmetics/Biocides, Certified Products

** 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

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| Article number | Article Name | 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 |
| 100675 | TENA Comfort Maxi Ps 52x1pcs AB | 7322541939780 |
| 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 |
| 211475 | TENA Comfort Original Maxi 2x28 pcs, Neutral | 7322540710755 |
| 211476 | TENA Comfort Original Plus 2x46 pcs, Neutral | 7322540710694 |
| 211518 | TENA Comfort Original Maxi 2x34pNeutral | 7322541752822 |
| 211522 | TENA Comfort Original Maxi 2x34p,INT | 7322541752822 |
| 211526 | TENA Comfort Original ValueExtraP 2x40pN | 7322541809564 |
| 211527 | TENA Comfort Original Value Ultima 2x28N | 7322541810126 |
| 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 |



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|---|---|---|
| 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 |
| 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 |
| 752744 | TENA Comfort Plus Comp 3x42pcs, Neu NSW | 7322541798943 |
| 752846 | TENA Comfort Plus 2x46 pcs INT | 7322540696035 |
| 752859 | TENA Comfort Plus 20x40 pcs IT | 7322540736892 |
| 753040 | TENA Comfort Extra 2x40 pcs INT | 7322540696196 |
| 758006 | TENA Comfort Maxi, 2x34pcs, Neutral | 7322541751900 |
| 758007 | TENA Comfort Maxi, 2x34pcs, INT/IT | 7322541751900 |
| 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 |
| 759007 | TENA Comfort Normal, 3x42pcs, Neutral | 7322541460758 |
| 759008 | TENA Comfort Plus, 2x46 pcs, Neutral | 7322541460871 |
| 759009 | TENA Comfort Extra, 2x40p, Neutral | 7322541461236 |
| 759010 | TENA Comfort Super, 2x36pcs, Neutral | 7322541461038 |
| 759011 | TENA Comfort Ultima, 2x26pcs, Neutral | 7322541461120 |
| 759012 | TENA Comfort Maxi, 2x28pcs, Neutral | 7322541461212 |
| 759128 | TENA Comfort Maxi 2x28 pcs INT | 7322540696219 |



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