

# EU DECLARATION OF CONFORMITY

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

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.

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

**Essity Hygiene and Health AB**  
SE-405 03 GÖTEBORG  
Sweden  
Visitors' address: Mölndals Bro 2, Mölndal  
Phone: +46 31 746 00 00  
[www.essity.com](http://www.essity.com)

| Document Name             | Document ID | Version |
|---------------------------|-------------|---------|
| Declaration of Conformity | FORM-00733  | 6.0     |

| 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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|---------------------------|-------------|---------|
| Document Name             | Document ID | Version |
| Declaration of Conformity | FORM-00733  | 6.0     |

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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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