

# 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 Flex 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 7322540100726T.

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

Mölndal, on 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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Sweden  
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 number
100008	TENA Flex Maxi Large 48x1pcs AB	7322541218328
100269	TENA Flex Plus Medium 60x1pcs AB	7322541257778
100270	TENA Flex Super Large 60x1pcs AB	7322541257884
100404	TENA Flex Plus XL 60x1pcs AB	7322541280011
100405	TENA Flex Plus Small 60x1pcs AB	7322541280158
100406	TENA Flex Plus Medium 60x1pcs ES	7322541280240
100407	TENA Flex Plus Large 60x1pcs ES	7322541280363
100408	TENA Flex Plus Large 60x1pcs AB	7322541280479
100409	TENA Flex Normal Medium 68x1pcs AB	7322541280561
100410	TENA Flex Normal Large 68x1pcs AB	7322541280653
100411	TENA Flex Maxi XL 48x1pcs AB	7322541280783
100412	TENA Flex Maxi Small 48x1pcs AB	7322541280929
100413	TENA Flex Maxi Medium 48x1pcs AB	7322541281032
100437	TENA Flex Ultima XL 40x1pcs AB	7322541293769
100438	TENA Flex Ultima Small 40x1pcs AB	7322541293868
100439	TENA Flex Ultima Medium 40x1pcs AB	7322541293974
100440	TENA Flex Ultima Large 40x1pcs AB	7322541294087
100441	TENA Flex Super XL 60x1pcs AB	7322541294193
100442	TENA Flex Super Small 60x1pcs AB	7322541294339
100443	TENA Flex Super Medium 60x1pcs ES	7322541294452
100444	TENA Flex Super Medium 60x1pcs AB	7322541294568
100445	TENA Flex Super Large 60x1pcs ES	7322541294681
100455	TENA Flex Plus Medium 60x1pcs C	7322541309514
100456	TENA Flex Plus Large 60x1pcs C	7322541309620
100457	TENA Flex Super Medium 60x1pcs C	7322541309736
100458	TENA Flex Super Large 60x1pcs C	7322541309842
100459	TENA Flex Maxi Medium 48x1pcs C	7322541309958
100460	TENA Flex Maxi Large 48x1pcs C	7322541310169
720000	TENA Flex Belt Extension 12x10pcs	7322540065091
720240	TENA Flex Elastico Plus M 4x20p, ProSkin	7310791260297
720349	TENA Flex Elastico Plus L 4x20p,ProSkin	7322540036459
720421	TENA Flex Elastico Super M 4x20p,ProSkin	7322540928297
720422	TENA Flex Plus Small 3x30pcs, JP	7322541014906
720430	TENA Flex Plus Medium 3x30pcs, JP	7322541015002
720512	TENA Flex Plus Large 3x30pcs, JP	7322541015101
720513	TENA Flex Plus S 3x30p, IT	7322541086835
720514	TENA Flex Plus S 3x30p, INT/NEU NSW	7322540125283
720515	TENA Flex Plus M 3x30p, IT	7322541087160

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Declaration of Conformity	FORM-00733	4.0

720516	TENA Flex Plus M 3x30p, INT/NEU NSW	7322540054651
720517	TENA Flex Plus L 3x30p, IT	7322541087467
720518	TENA Flex Plus L 3x30p, INT/NEU NSW	7322540054675
720519	TENA Flex Plus XL 3x30p, INT/NEU NSW	7322540202519
722234	TENA Flex Normal M 3x34p, INT	7322540769838
722334	TENA Flex Normal L 3x34p, INT	7322540769852
722360	TENA Flex Normal M 3x34p, INT/NEU NSW	7322540769838
722393	TENA Flex Normal L 3x34p, INT/NEU NSW	7322540769852
723130	TENA Flex Plus S 3x30p, INT	7322540125283
723230	TENA Flex Plus M 3x30p, INT	7322540054651
723330	TENA Flex Plus L 3x30p, INT	7322540054675
723430	TENA Flex Plus XL 3x30p, INT	7322540202519
724052	TENA Flex Super Small 3x30pcs, JP	7322541015231
724130	TENA Flex Super S 3x30p, INT	7322540394467
724230	TENA Flex Super M 3x30p, INT	7322540390575
724320	TENA Flex Super Medium 3x30pcs, JP	7322541015323
724321	TENA Flex Super Large 3x30pcs, JP	7322541015439
724330	TENA Flex Super L 3x30p, INT	7322540390599
724340	TENA Flex Elastico Super L 4x20p,ProSkin	7322540054712
724430	TENA Flex Super XL 3x30p, INT	7322540398724
724857	TENA Flex Super S 3x30p, IT	7322541087917
724900	TENA Flex Super S 3x30p, INT/NEU NSW	7322540394467
724901	TENA Flex Super M 3x30p, IT	7322541088167
724910	TENA Flex Super M 3x30p, INT/NEU NSW	7322540390575
724920	TENA Flex Super L 3x30p, IT	7322541088365
724930	TENA Flex Super L 3x30p, INT/NEU NSW	7322540390599
724940	TENA Flex Super XL 3x30p, INT/NEU NSW	7322540398724
725122	TENA Flex Maxi S 3x22p, INT	7322540129489
725130	TENA Flex Ultima S 3x20pcs, INT/NEU NSW	7322540884814
725194	TENA Flex Maxi Small 3x22pcs, JP	7322541015569
725195	TENA Flex Maxi Medium 3x22pcs, JP	7322541015668
725196	TENA Flex Maxi Large 3x22pcs, JP	7322541015767
725220	TENA Flex Ultima M 3x20p, INT/NEU NSW	7322540614893
725222	TENA Flex Maxi M 3x22p, INT	7322540079258
725228	TENA Flex Maxi S 3x22p, INT/NEU NSW	7322540129489

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Declaration of Conformity	FORM-00733	4.0

725229	TENA Flex Maxi M 3x22p, INT/NEU NSW	7322540079258
725230	TENA Flex Maxi L 3x22p, INT/NEU NSW	7322540079296
725231	TENA Flex Maxi XL 3x21p, INT/NEU NSW	7322540118971
725320	TENA Flex Ultima L 3x20p, INT/NEU NSW	7322540615418
725322	TENA Flex Maxi L 3x22p, INT	7322540079296
725360	TENA Flex Ultima Small 3x20pcs, JP	7322540897944
725400	TENA Flex Ultima XL 3x17p, INT/NEU NSW	7322540884838
725421	TENA Flex Maxi XL 3x21p, INT	7322540118971
725460	TENA Flex Ultima Medium 3x20pcs, JP	7322540818635
725548	TENA FLEX Ultima S 3x20p, INT	7322540884814
725560	TENA Flex Ultima Large 3x20pcs, JP	7322540818659
726843	TENA FLEX Ultima M 3x20p, INT	7322540614893
727505	TENA Flex Normal Plus L 3x30 INT NEU NSW	7322541112398
727506	TENA FLEX Ultima L 3x20p, INT	7322540615418
728001	TENA Flex Super Plus L 3x22p INT NEU NSW	7322541112862
728002	TENA Flex Super Plus XL 3x21 INT NEU NSW	7322541112992
750506	TENA Flex Maxi Large Basic	7322541230245
750507	TENA Flex Super Medium Basic	7322541230252
750508	TENA Flex Maxi Large Discreet	7322541230269
750509	TENA Flex Maxi Medium Discreet	7322541230276
750510	TENA Flex Super Large Discreet	7322541230283
750511	TENA Flex Super Medium Discreet	7322541230290
750513	TENA Flex Plus Large Discreet	7322541230306
750514	TENA Flex Plus Medium Discreet	7322541230313
750516	TENA Flex Plus Small Discreet	7322541230320
750517	TENA Flex Normal XL	7322541230337
750518	TENA Flex Normal S	7322541230344

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# EU 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 Flex Inkontinenční kalhotky s páskem na suchý zip 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 7322540100726T.

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

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Název dokumentu	ID dokumentu	Verze
Prohlášení o shodě	FORMULÁŘ 00733	4.0

Číslo položky	Položka	Číslo UDI-DI
100008	TENA Flex Maxi Large 48x1pcs AB	7322541218328
100269	TENA Flex Plus Medium 60x1pcs AB	7322541257778
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720515	TENA Flex Plus M 3x30p, IT	7322541087160

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750514	TENA Flex Plus Medium Discreet	7322541230313
750516	TENA Flex Plus Small Discreet	7322541230320
750517	TENA Flex Normal XL	7322541230337
750518	TENA Flex Normal S	7322541230344

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