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 Flex
Basic UDI-DI:	7322540100726T
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:	T04010103
Signatory:	Mölndal, on 2022-06-27 Romana Stefek Global Regulatory Affairs/Product Safety Director PRRC, LM Essity Hygiene and Health AB

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

This declaration is valid until new version is issued.

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Seat: Göteborgs kommun. Registration number: SE556007-2356

Heruntergeladen von Gast (IP 216.73.216.59) am 31.10.2026 um 10:43 Uhr · sana.swiss

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
100630	TENA Flex Ultima XL 40x1pcs AB	7322541775371
100631	TENA Flex Ultima Small 40x1pcs AB	7322541785462
100632	TENA Flex Ultima Medium 40x1pcs AB	7322541783994
100633	TENA Flex Ultima Large 40x1pcs AB	7322541784090
100634	TENA Flex Super XL 60x1pcs AB	7322541784748
100635	TENA Flex Super Small 60x1pcs AB	7322541784830
100636	TENA Flex Super Medium 60x1pcs ES	7322541784939
100637	TENA Flex Super Medium 60x1pcs AB	7322541785455
100638	TENA Flex Super Large 60x1pcs ES	7322541785219
100639	TENA Flex Plus XL 60x1pcs AB	7322541795546
100640	TENA Flex Plus Small 60x1pcs AB	7322541795652
100641	TENA Flex Plus Medium 60x1pcs ES	7322541795751
100642	TENA Flex Plus Large 60x1pcs ES	7322541795843

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100643	TENA Flex Plus Large 60x1pcs AB	7322541795942
100644	TENA Flex Normal Medium 68x1pcs AB	7322541796055
100645	TENA Flex Normal Large 68x1pcs AB	7322541796161
100646	TENA Flex Maxi XL 48x1pcs AB	7322541796277
100647	TENA Flex Maxi Small 48x1pcs AB	7322541796383
100648	TENA Flex Maxi Medium 48x1pcs AB	7322541796499
100649	TENA Flex Maxi Large 48x1pcs AB	7322541796604
100650	TENA Flex Plus Medium 60x1pcs AB	7322541796772
100651	TENA Flex Super Large 60x1pcs AB	7322541796888
100652	TENA Flex Plus Medium 60x1pcs C	7322541797137
100653	TENA Flex Plus Large 60x1pcs C	7322541797298
100654	TENA Flex Super Medium 60x1pcs C	7322541797380
100655	TENA Flex Super Large 60x1pcs C	7322541797489
100656	TENA Flex Maxi Medium 48x1pcs C	7322541797571
100657	TENA Flex Maxi Large 48x1pcs C	7322541797663
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
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
720520	TENA Flex Elastico Plus M 4x20p,ProSkin	7322541422817
720521	TENA Flex Elastico Plus L 4x20p,ProSkin	7322541422930
720522	TENA Flex Elastico Super M 4x20p,ProSkin	7322541423043
720523	TENA Flex Elastico Super L 4x20p,ProSkin	7322541423166
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
722394	TENA Flex Normal L 3x34p INT/NEU NSW	7322541405537
722514	TENA Flex Normal L 3x34p INT NSW	7322541405537
723130	TENA Flex Plus S 3x30p, INT	7322540125283
723230	TENA Flex Plus M 3x30p, INT	7322540054651
723330	TENA Flex Plus L 3x30p, INT	7322540054675

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723333	TENA Flex Plus L 3x30p INT NSW	7322541405759
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
724950	TENA Flex Plus XL 3x30p INT NSW	7322541404646
724960	TENA Flex Plus XL 3x30p INT/NEU NSW	7322541404646
724970	TENA Flex Super XL 3x30p INT/NEU NSW	7322541404967
724980	TENA Flex Super XL 3x30p INT NSW	7322541404967
725000	TENA Flex Maxi XL 3x21p INT NSW	7322541405209
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
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

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727505	TENA Flex Normal Plus L 3x30 INT NEU NSW	7322541112398
727506	TENA FLEX Ultima L 3x20p, INT	7322540615418
727507	TENA Flex Maxi M 3x22p INT ProSkin	7322541320625
727508	TENA Flex Maxi L 3x22p INT ProSkin	7322541320861
728001	TENA Flex Super Plus L 3x22p INT NEU NSW	7322541112862
728002	TENA Flex Super Plus XL 3x21 INT NEU NSW	7322541112992
728312	TENA Flex Maxi XL 3x21p INT ProSkin	7322541320847
728533	TENA Flex Maxi XL 3x21p INT/NEU NSW	7322541405209
728534	TENA Flex Ultima XL 3x17p INT/NEU NSW	7322541405438
728599	TENA Flex Plus L 3x30p INT/NEU NSW	7322541405759
728694	TENA Flex Plus L 3x30p IT NSW	7322541405957
728695	TENA Flex Super L 3x30p INT/NEU NSW	7322541406077
728749	TENA Flex Super L 3x30p IT NSW	7322541406169
729281	TENA Flex Super L 3x30p INT NSW	7322541406077
729352	TENA Flex Maxi L 3x22p INT NSW	7322541406411
729620	TENA Flex Maxi L 3x22p INT/NEU NSW	7322541406411
729695	TENA Flex Ultima L 3x20p INT NSW	7322541406633
729909	TENA Flex Ultima L 3x20p INT/NEU NSW	7322541406633
730082	TENA Flex Normal M 3x34p INT/NEU NSW	7322541406886
730369	TENA Flex Normal M 3x34p INT NSW	7322541406886
730430	TENA Flex Plus M 3x30p INT NSW	7322541407104
730431	TENA Flex Plus M 3x30p INT/NEU NSW	7322541407104
730432	TENA Flex Plus M 3x30p IT NSW	7322541407319
730433	TENA Flex Maxi M 3x22p INT/NEU, NSW	7322541407432
730434	TENA Flex Maxi M 3x22p INT NSW	7322541407432
730435	TENA Flex Ultima M 3x20p INT NSW	7322541407678
730436	TENA Flex Ultima M 3x20p INT/NEU NSW	7322541407678
730437	TENA Flex Plus S 3x30p INT NSW	7322541407951
730438	TENA Flex Plus S 3x30p INT/NEU NSW	7322541407951
730439	TENA Flex Plus S 3x30p IT NSW	7322541408170
730440	TENA Flex Super S 3x30p INT/NEU NSW	7322541408644
730445	TENA Flex Super S 3x30p IT NSW	7322541408552
730446	TENA Flex Super S 3x30p INT NSW	7322541408644
730447	TENA Flex Maxi S 3x22p INT/NEU NSW	7322541410449
730453	TENA Flex Maxi S 3x22p INT NSW	7322541410449
730454	TENA Flex Ultima S 3x20p INT NSW	7322541410548
730455	TENA Flex Ultima S 3x20p INT/NEU NSW	7322541410548
730456	TENA Flex Super M 3x30p INT/NEU NSW	7322541410937
730457	TENA Flex Super M 3x30p IT NSW	7322541411026
730458	TENA Flex Super M 3x30p INT NSW	7322541410937
750506	TENA Flex Maxi Large Basic	7322541230245
750507	TENA Flex Super Medium Basic	7322541230252

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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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