



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- Single Registration Number (SRN)	DK-MF-000002482	

### Medical Device(s)


- Basic UDI-DI	Please see appendix I
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- Intended Purpose	Please see appendix I
- Risk classification	Class I according to rule no. 1 in MDR annex II

### Other information (if applicable)

- Common Specifications used for compliance	ISO 13485:2016
- Notified Body name and identification no. and description of the conformity assessment procedure performed	N/A
- Additional information	N/A
- Standards used to assure compliance	Please see appendix II

The above mentioned manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

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

Name and Function: <b>Ane Kirstine Schmidt, Category Manager</b>	<b>Place and date of issue</b> Aabenraa, DK, 01.06.2021
Signature  Abena, Egelund 35, DK-6200 Aabenraa	

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### Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose
Shoe cover, L, white	210854	57035380ShCoD-00I-06001MH	The shoe cover is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.

*expand list accordingly*

### Appendix II, List of applicable standards used

Product Name	Standards used
All products listed in Appendix 1	MDR EU 2017/745
	ENISO 14971:2019
	ISO10993-1:2018
	ISO10993-5:2009
	ISO10993-10:2013
	DS/EN 1041 + A1:2013
	ENISO15223-1:2016
	<i>expand list accordingly</i>

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