



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- Phone / fax / email / webpage	DK-6200 Aabenraa Denmark	Fax: +45 7462 9737 Mail: info@abena.com
- Single Registration Number (SRN)	DK-MF-000002482	

### Medical Device(s)

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


### Other information (if applicable)

- Common Specifications used for compliance	ISO 13485:2016
- Compliance to other legislations	N/A
- 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

- EU Regulation 2017/745 on Medical Devices
- UK Medical Device Regulation 2002
- EU 2016/425 CE CAT I For minimal risk only, Module A – Manufacturers self-declaration

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

Name and Function: <b>Tina Jønson, Global Category Manager</b>	<b>Place and date of issue</b> Aabenraa, DK, 20.04.2023
Signature  Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO
File: DoC External MDR_PPE - Headwear, ver. 04	Revision/Version: 1.5
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### Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose	EMDN no	EMDN term description
Clip cap, L, blue	210600	57035380HeaWD-00I-06001BD	Clip caps are used to protect the environment where a high standard of hygiene is needed.	T0207	Caps and Headwear
Clip cap, L, white	210601				
Clip cap, L, red	210602				
Clip cap, L, yellow	210603				
Clip cap, L, green	210604				
Clip cap, XL, white	1999906762				
Clip cap, XL, blue	1999906765				
Clip cap, XL, red	1999911635				
Clip cap, XL, green	1999911636				
Clip cap, XL, yellow	1999911637				
Bouffant cap, L, white	210750		Bouffant caps are used to protect the environment where a high standard of hygiene is needed.		
Bouffant cap, L, blue	210751				
Bouffant cap, L, green	210752				
Beard cover, one size, white	210681		Beard cover with elastic are used to protect the environment where a high standard of hygiene is needed.		
Beard cover, L, white	1999905492				
Beard cover, XL, white	1999904888				
Nurse cap, one size, blue	210760		Nurse caps are used to protect the environment where a high standard of hygiene is needed.		
Doctor cap, one size, blue	210771		Doctor cap with sweat band and ties in the neck, used to protect the		
Doctor cap, one size, blue	210772				

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Doctor cap, one size, multi color	1999913696		environment where a high standard of hygiene is needed.		
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### Appendix II, List of applicable standards used

Standard title	No. and year
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1:2016
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2018
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013

*expand list accordingly*

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