



EU Declaration of Conformity

Legal Manufacturer

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- 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

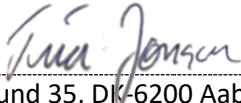
Other information (if applicable)

- Common Specifications used for compliance	N/A
- Compliance to other legislations	UK Medical Device Regulation 2002, SI 2002 No 618, as amended.
- 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

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

Name and Function: Tina Jønson, Global Category Manager	Place and date of issue Aabenraa, DK, 23.10.2023
Signature  Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Warming jacket with short sleeves, S, Blue	210520	Warming jackets intended for use by healthcare staff to avoid cross contamination.	T0299	Protection drapes and garments - Other	57035380JackD-00I-06001UU
Warming jacket with short sleeves, M, Blue	210521				
Warming jacket with short sleeves, L, Blue	210522				
Warming jacket with short sleeves, XL, Blue	210523				
Warming jacket with short sleeves, XXL, Blue	210524				
Warming jacket with long sleeves, S, Blue	1000008970				
Warming jacket with long sleeves, M, Blue	1000008971				
Warming jacket with long sleeves, L, Blue	1000008972				
Warming jacket with long sleeves, XL, Blue	1000008973				
Warming jacket with long sleeves, XXL, Blue	1000008974				
Warming jacket with short sleeves, XS, Blue	1010001212				
Warming jacket with long sleeves, ABENA Excellent, M, green	1010002017				
Warming jacket with long sleeves, ABENA Excellent, L, green	1010002018				
Warming jacket with long sleeves, ABENA Excellent, XL, green	1010002019				
Warming jacket with short sleeves, S, dark blue	1999915953				
Warming jacket with short sleeves, M, dark blue	1999915954				
Warming jacket with short sleeves, L, dark blue	1999915955				
Warming jacket with short sleeves, XL, dark blue	1999915956				
Warming jacket with short sleeves, XXL, dark blue	1999915957				
Warming jacket with long sleeves, S, dark blue	1999916551				
Warming jacket with long sleeves, M, dark blue	1999916552				
Warming jacket with long sleeves, L, dark blue	1999916553				
Warming jacket with long sleeves, XL, dark blue	1999916554				
Warming jacket with long sleeves, XXL, dark blue	1999916555				

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Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
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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 15223-1:2021
Medical devices – Information to be supplied by the manufacturer	EN 20417:2021
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 skin sensitization	EN ISO 10993-10:2021

expand list accordingly

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