



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

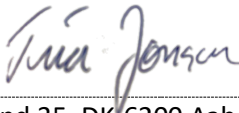
Other information (if applicable)

- Common Specifications used for compliance	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

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
Signature 	Aabenraa, DK, 30.03.2023
Abena, Egelund 35, DK-6200 Aabenraa	

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File: DoC External MDR - Medical face mask, ver. 02	Revision/Version: 1.5
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Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Medical face mask with elastic ear loops, type IIR	1000010123	The medical face mask are intended to be used in medical settings, to protect the patient from infective agents and the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.	T020604	Medical use face masks, Type II and IIR	57035380FacMD-00I-06008SE
Medical face mask ties, type IIR	1000010124				
Medical face mask with elastic ear loops, type IIR	1999903629				
Medical face mask with elastic ear loops, type IIR	1999902619				
Medical face mask with elastic ear loops, type II	220899	The medical face mask are intended to be used in medical settings, to protect the patient from infective agents. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.			57035380FacMD-00I-06007SC

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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
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 10993-1:2020
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
Biological evaluation – Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
Medical face masks - Requirements and test methods	EN 14683:2019 + AC:2019

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