EU Declaration of Conformity

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA A/S Egelund 35 DK-6200 Aabenraa Denmark	www.abena.com Phone: +45 7431 1818 Fax: +45 7462 9737 Mail: info@abena.com
- 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 mention 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:
Ane Kirstine Schmidt, Category Manager

Signature

Abena, Egelund 35, DK-6200 Aabenraa

Place and date of issue
Aabenraa, DK, 01.06.2021

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Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose
Medical face mask with elastic ear loops, type IIR	1000010123	57035380FacMD-00I-06008SE	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.
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 ties, type II	220898	57035380FacMD-00I-06007SC	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.
Medical face mask with elastic ear loops, type II	220899		

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
	EN14683:2019+AC:2019
	expand list accordingly

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