



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)	To be applied	

Medical Device(s)

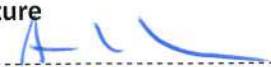
- Basic UDI-DI	To be applied
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Medical face mask, Abena, with ear loops, Type IIR
- Other ref. allowing identification (e.g. UDI-DI)	Abena art.no 1000010123-08, 1000010123-68 Abena art.no 1999902619-03, 1999902619-28, 1999902619-63
- Intended Purpose	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.
- Risk classification	Class I according to rule no. 1 in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	-
- Notified Body name and identification no. and description of the conformity assessment procedure performed	-
- Additional information	-
- Standards used to assure compliance	EN 14683:2019

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 	Place and date of issue Aabenraa, DK, 08.12.2020
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: DoC, External, MDR - 1000010123-08, 1999902619-03 - 20201208	Revision/Version: 1.1	Date: 19-08-2020
Copyright: Abena	Applicable SOP: n/a	Page 1/3

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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Medical face mask, Abena, with ear loops, Type IIR	1000010123-08 1000010123-68	To be applied	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, Abena, with ear loops, Type IIR	1999902619-03 1999902619-28 1999902619-63	To be applied	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.

expand list accordingly



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Appendix II, List of primary standards used

Product Name	Standards used
Medical face mask, Abena, with ear loops, Type IIR, art.no 1000010123-08, 1000010123-68	EN 14683:2019 EN ISO 13485 EN ISO 14971:2012 EN ISO 15223-1:2016 EN ISO 10993-5:2009 EN ISO 10993-10:2013
Medical face mask, Abena, with ear loops, Type IIR, retail, art.no 1999902619-03, 1999902619-28, 1999902619-63	EN 14683:2019 EN ISO 13485 EN ISO 14971:2012 EN ISO 15223-1:2016 EN ISO 10993-5:2009 EN ISO 10993-10:2013

expand list accordingly

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