

Article 22 Declaration

No.: REG-005641

Product Name(s):	Ambu® Mark IV
	Reusable resuscitator incl. face mask
Intended Purpose:	Intended for pulmonary resuscitation
REF number(s)	299006000 299007000 299008000 304002000 304009000 299001000 299003000
Basic UDI-DI	570748030101051006Z
GMDN	36690 – Cardiopulmonary resuscitation kit, reusable

We, the manufacturer, hereby declare that:

The above listed product(s) comply with the requirements of Article 22 Particular procedure for systems and procedure packs in the EU Regulation 2017/745 on Medical Devices.

Ambu has verified the mutual compatibility of the devices in accordance with the manufacturer's instructions and has carried out the operations in accordance with these instructions, and

Ambu has packed and supplied the System and Procedure Pack and supplied the relevant information to users incorporating relevant instructions from the manufacturers, and

The whole activity is subjected to appropriate methods of internal monitoring, verification and validation.

For and on behalf of Ambu A/S, Denmark

Ballerup
08.12.2022



Katrine Dalsgaard Ajbros, Head of Regulatory Affairs Operation

First Issued: 08 December 2022

Product name: Ambu® Mark IV					
REF number: 299006000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir bag, size baby	299011000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0A	000320000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 299007000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir bag, size baby	299011000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0	000322000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 299008000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir bag, size baby	299011000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0A	000320000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0	000322000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 304002000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir bag, size adult	304033000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 5	000326000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 304009000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir bag, size adult	304033000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 2	000323000	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 5	000326000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 299001000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir tube, size baby	299011001	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0A	000320000	Ambu A/S	IIa	1

Product name: Ambu® Mark IV					
REF number: 299003000					
Content					
Product Name	Version	Ref Number	Legal Manufacturer	Medical Device Class	Pcs
Ambu® Mark IV	Reservoir tube, size baby	299011001	Ambu A/S	IIa	1
Ambu® Silicone Face Mask	Size 0	000322000	Ambu A/S	IIa	1