

Article 22 Declaration

No.: REG-005440

Product Name: Ambu® SPUR® II

Product Description(s): Resuscitator with Reservoir Tube/
Resuscitator w. Reservoir Bag/
Resuscitator with Demand Valve Connector Inlet/
Resuscitator with Reservoir bag w/o M-port
Incl. Face Mask

Intended Purpose: Intended for pulmonary resuscitation

REF number(s)	325002000	330003000	325023000	335026000
	325014000	330004000	330023000	335003000
	325029000	330006000	330032000	335002000
	325011000	330009000	330021000	335025001
	325025000	330027000	325021000	330025000
	325022000	335103000	335028000	
	330002000	335102000	335027000	

Basic UDI-DI 570748030101001005W

GMDN 35693 – Cardiopulmonary resuscitation kit, single-use

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

Place
08-12-2022


Katrine Dalsgaard Ajbro
Head of Regulatory Affairs Operation

First Issued: 08-12-2022

Product name: Resuscitator with Reservoir bag w/o M-port				
REF number: 325021000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag w/o M-port	325807000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir bag w/o M-port				
REF number: 330021000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag w/o M-port	330807000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325002000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325014000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325029000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult S	000252963	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult L	000252962	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325011000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask without check valve, Adult M	000252064	Ambu A/S	IIa	1
Ambu® Disposable Face Mask without check valve, Adult L	000252066	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325025000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325110000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 325022000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	325114000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult L	000252962	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 330002000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	330107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 330003000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	330107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 330004000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	330107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 330006000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	335107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 330009000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	335107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask without check valve, Infant	000252058	Ambu A/S	IIa	1
Ambu® Disposable Face Mask without check valve, Toddler	000252059	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 335103000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	335107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator w. Reservoir Bag				
REF number: 335102000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	335107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1

Product name: Resuscitator with Demand Valve Connector Inlet				
REF number: 325023000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Demand Valve Connector Inlet	325207000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Adult M	000252961	Ambu A/S	IIa	1

Product name: Resuscitator with Demand Valve Connector Inlet				
REF number: 330023000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Demand Valve Connector Inlet	330207000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator with Demand Valve Connector Inlet				
REF number: 330032000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Demand Valve Connector Inlet	330207000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Tube				
REF number: 335028000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Tube	335707000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, neonate	000252957	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Tube				
REF number: 335027000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Tube	335707000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Tube				
REF number: 335026000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Tube	335707000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Tube				
REF number: 335002000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Tube	335507000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Tube				
REF number: 335003000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Tube	335507000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Bag				
REF number: 335025001				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Bag w PEEP Valve and Manometer	335407000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Bag				
REF number: 330025000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir Bag w PEEP Valve and Manometer	330410000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1

Product name: Resuscitator with Reservoir Bag				
REF number: 330027000				
Content				
Product Name/Description	Ref Number	Legal Manufacturer	Medical device Class	Pcs
Ambu® SPUR® II SPUR II Reservoir bag	330107000	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Neonate	000252957	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Infant	000252958	Ambu A/S	IIa	1
Ambu® Disposable Face Mask with check valve, Toddler	000252959	Ambu A/S	IIa	1