EU Medical Device System Statement of Compatibility

Responsible System Producer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway
Single Registration Number (SRN):	NO-PR-000002650
System Producer site:	Laerdal Medical (Suzhou) Co., Ltd. Building 18,19,20, No. 57 Huoju Road Science & Technology Industrial Park Suzhou, Jiangsu Province 215009 China

Systems:

84711040	The BAG Newborn Mask 1	12 pack
84722040	The BAG Pediatric Mask 2	12 pack
84723040	The BAG Pediatric Mask 3	12 pack
84734040	The BAG Adult Mask 4	12 pack
84735040	The BAG Adult Mask 5	12 pack
847110401	The BAG Newborn Mask 1	1 pack
847220401	The BAG Pediatric Mask 2	1 pack
847230401	The BAG Pediatric Mask 3	1 pack
847340401	The BAG Adult Mask 4	1 pack
847350401	The BAG Adult Mask 5	1 pack

Basic UDI-DI 0704543209970T5

The Systems to which this declaration relates contains the following medical devices:

Catalogue Number:	Name:	UDI-DI:
847100	The BAG Newborn Resuscitator	07045432116236
8470110	The BAG Mask #1	07045432116267
847200	The BAG Pediatric Resuscitator	07045432116243
8470120	The BAG Mask #2	07045432116274
847200	The BAG Pediatric Resuscitator	07045432116243
8470130	The BAG Mask #3	07045432116281
847300	The BAG Adult Resuscitator	07045432116250
8470140	The BAG Mask #4	07045432116298
847300	The BAG Adult Resuscitator	07045432116250
8470150	The BAG Mask #5	07045432116304

The medical devices included in the system have been verified to be mutually compatible when used in accordance with the manufacturers' instructions.

The system incorporates the information supplied by the manufacturers of the medical devices.

The system has been combined in conformance with the applicable processes of the Laerdal ISO 13485 certified Quality Management System.

This statement has been drawn up as defined in EU Regulation 2017/745, Article 22.

DocuSigned by:
Adrienne Farrington
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Adrienne Farrington
Regulatory Affairs Specialist
On behalf of Alf Christian Dybdhal,
CEO
20th March 2025
Stavanger, Norway