EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway
Single Registration Number:	NO-MF-000000012
Manufacturing site:	Laerdal Medical (Suzhou) Co. Ltd. Building 18,19,20, No. 57 Huoju Road Science & Technology Industrial Park Suzhou, Jiangsu Province 215009, China
Product Name:	**V-VAC Manual Suction Unit**
Basic UDI-DI:	0704543209942SY
Intended Purpose:	The V-VAC is a manual suction device intended for pharyngeal suction. V-VAC is a portable unit designed to provide quick and effective emergency suction in situations where conventional powered apparatus cannot be used or is not available. Together with the suction tip adapter and double male connector the V-VAC offers a complete manual suction solution when used with a catheter.

Product Options:

985300 V-VAC Manual Suction Unit

Medical Device Accessories:

985200 V-VAC Carrying Bag (Yellow)
985002 V-VAC Adapter Tips (pack of 4)
985003 V-VAC Double Male Connectors (pack of 10)

to which this declaration relates is in conformity with the General Safety and Performance Requirements of EU Regulation 2017/745

Classification:

V-VAC Suction Unit and the accessories are class I according to rule 5 of Annex VIII of the EU Medical Device Regulation.

Conformity Assessment is based on the principles described in Article 52 of Regulation 2017/745

Conformity is declared in relation to common Specification(s):

No Common Specification has been published for manual suction units.

This EU Declaration of Conformity is issued under the sole responsibility of Laerdal Medical AS.

DocuSigned by:
Mari Kaada
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Mari Kaada

Corporate Director Q&R
On behalf of Alf Christian Dybdahl, CEO
25.05.2021

Stavanger, Norway

CE

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