EU DECLARATION OF CONFORMITY

Responsible Manufacturer: Laerdal Medical AS
P.O. Box 377
Tanke Svilandsgate 30
4002 Stavanger
Norway

Single Registration Number (SRN): *Not assigned at this time*

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: Thomas Tube Holder

Basic UDI-DI: 0704543209934SZ

Intended Purpose: The Thomas Tube Holder is designed to secure single and double-lumen airway tubes and reduce the risk of accidental dislodgement.

Product Options:

600-10000	Thomas Tube Holder Adult (International) qty.1)
600-20000	Thomas Tube Holder Pedi (International) qty.1
600-30000	Thomas Tube Holder Adult green (Int'l) qty.1

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

Classification: Thomas Tube Holder is class I according to rule 5 of Annex VIII of the EU Medical Device Regulation.

Laerdal Medical AS is certified by DNV GL Presafe AS to ISO 13485: 2016.
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 CS available at this time

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

Stavanger, 2 March 2020

Mari Kaada
Corporate Director Q&R
on behalf of Tore Lærdal, CEO

CE