00026869 Rev E

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 date*

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 Select

Basic UDI-DI: 0704543209935T3

Intended Purpose: Thomas Select shall accommodate fixation for supraglottic airway devices size 3-6 and tracheal tubes from size 6.5mm and larger (inner diameter).

Product Options:

600-40000	Thomas Select Tubeholder Adult
600-40005	Thomas Select Tubeholder Adult Japanese version
600-42500	Thomas Select Tubeholder Adult 25pk
600-42505	Thomas Select Tubeholder Adult 25pk Japanese version

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

Classification: Thomas Select 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