

DECLARATION OF CONFORMITY

In according with EC Medical Device Directive 93/42/EEC (June 14, 1993)

We herewith declare that the below mentioned Medical Device is in conformity with the stated standards and the essential requirements of EC Medical Device Directive 93/42/EEC as amended by 2007/47/EC and 2023/607.

Classification: Class IIa MDD Annex IX Rule 5

MDD Certificate:

CE77043 (Full Quality Assurance System) **Affixed:** 26 Feb 2019 **Exp:** 18 Sep 2023
MDD Extension (EU2023/607) **Affixed:** 22 Aug 2023 **Exp:** 31 Dec 2028

Conformity Assessment Route: MDD 93/42/EEC, Annex II, Excluding Section 4 (CE77043)

Product Name: ENDOTRACHEAL TUBE, UNIVENT TUBE, TCB Type

Product #	Model Name	Size / Type
1202716	ENDOTRACHEAL TUBE, UNIVENT TUBE (TCB Type)	3.5mm without cuff
1202720		4.5mm with cuff
1202927		6.0mm
1202928		6.5mm
1202930		7.0mm
1202931		7.5mm
1202933		8.0mm
1202935		8.5mm
1202936		9.0mm
1202937		9.5mm
1202939		10.0mm

GMDN Code: 31328 Endobronchial tube

UMDNS Code: 14085 Tubes, Tracheal

Notified Body : British Standards Institution (BSI Group The Netherlands B.V.)

NB No. : 2797

Address : John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Standards applied BS EN ISO 13485 (2016) BS EN 62366 (2008) ISO 15223-1 (2016)
: BS EN 1041 (2008) BS EN ISO 14971 (2012) ISO 10993-1 (2009)
ISO 11135 (2014) ISO 10993-7 (2008)
ISO 11607-1,2 (2006) ISO 5356-1 (2015)

Authorized Representative: MedDevConsult GmbH

Address: Airport Center (Building C) Flughafenstrasse 52a 22335 Hamburg Germany

Manufacturer: Fuji Systems Corporation, Shirakawa Plant

Address: 200-2 Aza-Ohira, Odakura, Nishigo, Nishi Shirakawa Gun, Fukushima 961-8061 Japan

Fuji Systems Corporation

Sign;

Shingo Ueki
Plant Manager, Director

Date: 27. Oct. 2023