

EC DECLARATION OF CONFORMITY

With regard to MDD 93/42/EEC as amended and Article 120 of MDR 2017/745 for medical devices

Name of the company : Medical Technology Transfer and Services Company Limited
Address : No 26, Lane 41, An Duong Vuong, Tay Ho District, Hanoi
Product name : Neonatal bubble CPAP
Brand name : Dolphin CPAP
Model : CPAP – V1.20
Basic UDI-DI : 111720643880
Risk class : I Ib
as per annexure IX of MDD 93/42/EEC, section 4 Rule 11 (Active device intended to administer and/or remove medicines, body liquids or other substances to or from the body)



We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and fulfills the essential requirements of MDD 93/42/EEC as amended by 2007/47/EC and transitional provisions in Article 120 of MDR 2017/745.

We have presented our product and our system to Notified Body 3EC (2265) for conformity assessment as per Annexure II, excluding (4), of MDD 93/42/EEC as amended by 2007/47/EC and Article 120 of MDR 2017/745.

This declaration is based on

EN ISO 13485:2016, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010 + A1:2015, EN 60601-1-8:2007 + A1:2013 + A11:2017, ISO 10993-1:2009, EN ISO 14971:2012, IEC 62304:2006, ISO 15223-1:2016, EN 1041:2008 + A1:2013, EN ISO 8185:2009, EN ISO 80601-2-61:2011, EN 22248:1993, ISO 2234:2000, ISO 2875:2000, EN 28768:1993, ISO 10531:1992, ISO 2244:2000, MEDDEV 2.12-1 Rev. 8, MEDDEV. 2.7.1 Rev.4.

Notified Body:

**3EC International a.s., Hraničná 18, 821 05
Bratislava, Slovak Republic**
Notified Body No. 2265

EU Representative:

Logic s.r.l
Via Antonio Pigafetta 1, 34147 Trieste,
Italy

Place of Issue : Hanoi, Vietnam
Manufacturer : Medical Technology Transfer and Services Company Limited
Name : Gregory Dajer, Director
Signature :

Date : 20.05.2022