Declaration of Conformity

Manufacturers Name and Business Address:	SLE Limited, Twin bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL United Kingdom.
Medical Device(s):	SLE6000 Infant Ventilator
Additional Device Information:	Refer to Appendix 1 for additional information.

This declaration of conformity is issued under the sole responsibility of the manufacturer of the device(s) listed in this document.

We the manufacturer hereby declare that these product(s) conform with the relevant provisions of the directive 93/42/EEC of June 14, 1993 as transposed into UK law by Statutory Instrument S.I. 2008 No. 2936 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning medical devices as transposed into national regulations and by subsequent directives, laws, and other national regulations.

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002. Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied. The scope of application covers all devices.

EU Risk Classification and Rule:	Class IIb, Rule 9, Rule 10, and Rule 11
Conformity Assessment:	Annex II (excluding section 4) The Notified Body listed has been appointed to undertake activities pursuant to the specified annex.
Notified Body:	BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands NB Registration Number: 2797
Certificate Number(s):	Quality System Certificate MD689407, EC Certificate CE688636
Standards Applied:	Refer to Appendix 1 for list of standards applied
Declaration of Conformity is valid until:	This Declaration of Conformity is valid until: 08 April 2022
Authorised Signatory:	For and on behalf of SLE Limited. Issued at the listed manufacturer address.

Signature: _____ Title: QA/RA Manager

Name: Timothy Bubb Date of Issue: 19 February 2019

Digitally signed by Prodan Sveatoslav
Date: 2024.08.29 16:59:55 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Appendix 1: Declaration of Conformity Product List

Product Identifier	Product Description	Risk Class and Rule	Conformity Assessment	EC Certificate Category	List of Standards Applied	Date added to List	GMDN Code
Z6000	SLE6000 Infant Ventilator with Core Configuration Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	21 Sept 2016	14361
Z6000/SLN	SLE6000 Single Limb NIV Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	21 Sept 2016	40582
Z6000/O2T	SLE6000 Oxygen Therapy Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	21 Sept 2016	40582
Z6000/VTV	SLE6000 VTV (Conventional Ventilation) Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	21 Sept 2016	40582
Z6000/HFO	SLE6000 HFOV Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	21 Sept 2016	40582
Z6000/NIP	SLE6000 NIPPV Tr. Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	07 Aug 2018	40582
Z6000/SPO	SLE6000 Masimo SpO2 Monitoring Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	07 Aug 2018	40582
Z6000/ETC	SLE6000 ETCO2 Monitoring Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	07 Aug 2018	40582
Z6000/CLP	SLE6000 Oxygenie Auto FiO2 Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	07 Aug 2018	40582
Z6000/ITB	SLE6000 Philips Intellivue/Intellibridge Software Module	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Lung Ventilators	Refer to [RAF104]	07 Aug 2018	40582
L6000/SP2/001	SLE6000 uSpo2 Cable (Masimo SET)	Class IIb, Rule 9, 10, and 11	Annex II (excluding section 4)	Pulse Oximeter Module	Refer to [RAF99]	17 Aug 2018	36554

GMDN	GMDN Description
14361	Neonatal intensive-care ventilator
40582	Ventilator application software
36554	Patient monitoring system module, pulse oximetry