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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734803 R000

Manufacturer: Vyaire Medical, Inc

Address:
26125 N. Riverwoods Blvd
Mettawa
Illinois
60045
USA

Single Registration Number: US-MF-000008254

EU Authorised Representative: Emergo Europe

Address:
Prinsessegracht 20
2514 AP
The Hague
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-04-22** Date: **2022-04-22** Expiry Date: **2027-04-21**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Bellavista ventilator BV 1000, 1000e	The Bellavista ventilator was developed for ventilating adult and paediatric patients. Also neonatal patients with a tidal volume ≥2 mL. The device is intended for use in clinics and institutional facilities where medically trained professionals are available for attending to the patient. The device can be used at the bedside, as well as for transferal within a facility, when a patient is in need of oxygen.
Bellavista ventilator BV 1000neo	The Bellavista 1000 neo ventilator was developed for ventilating neonatal patients of a tidal volume of ≥2 mL. The device is intended for use in clinics and institutional facilities where medically trained professionals are available for attending to the patient. The device can be used at the bedside, as well as for transferal within a facility, when a patient is in need of oxygen.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Flow sensor	Class IIa
SuperNO2VA Et mask & system	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3277241	Issued

First Issued: **2022-04-22** Date: **2022-04-22** Expiry Date: **2027-04-21**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 734803 R000

Date: **2022-04-22**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
IMT AG Gewerbestrasse 8 9470 Buchs (SG) Switzerland	**Design** **Development**
Productos Urológos de Mexico S.A. de C.V. Cerrada Via de la Produccion No. 85 Parque Industrial Mexicali III Baja California CP 21397 Mexico	**Manufacture**
Technocom Systems Sdn Bhd Plo 1, Jalan Firma 1, Kawasan Perindustrian Tebrau 1, 81100 Johor Bahru Malaysia	**Assembly**
Venture Corporation Limited Block 5006, Ang Mo Kio Avenue 5 #05-01/12 TECHplace II 569873 Singapore	**Assembly**
Vyaire Medical, Inc. 510 Technology Drive Irvine California 92618 USA	**Design** **Development**

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