

Certificate GB21/968568

The quality management system of

BPR Medical Ltd

22 Hamilton Way Mansfield Nottinghamshire NG18 5BU United Kingdom

Facility identification number : F003810

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

Design, Manufacture and Service of medical gas therapy devices for respiratory therapy and for pain management.

This certificate is valid from

Effective Date: 19 April 2022 until Expiry Date: 07 February 2024

and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 03 January 2024

Issue 3. Certified since 20 April 2021.

Authorised by

L. Henderson

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