



Certificate Number GB21/968568
The quality management system of

BPR Medical Ltd

22 Hamilton Way, Mansfield, Nottinghamshire, NG18 5BU, UK

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: 2021-04-20 until Expiry Date: 2024-02-07
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-01-03

Issue 1. Certified since 2021-04-20

Authorised by L Henderson
Business Manager

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