

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Huntleigh Healthcare Ltd
35 Portmanmoor Road
Cardiff
CF24 5HN
United Kingdom

Holds Certificate Number:

MD 718001

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, service and distribution of monitoring, diagnostic and treatment equipment, including: Doppler devices and their associated sterile and non-sterile accessories, Vital signs monitors, fetal monitors, vascular assessment devices, vascular treatment devices and associated non-sterile accessories.
Design, development and distribution of associated software.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-06-12

Latest Revision Date: 2024-11-20

Effective Date: 2024-12-17

Expiry Date: 2027-12-16

