EC Certificate Full Quality Assurance System: Certificate GB19/964252



The management system of

PMD Device Solutions Limited trading as PMD Solutions

Bishopstown House, Model Farm Road, Cork, T12 T922, Ireland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

RespiraSense patient respiratory monitor system.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 24 May 2021 until 14 November 2023 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 14 November 2014

Certification is based on reports numbered GB/PC 232336

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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