

Medical Device Production Quality Assurance System Certificate
GB23/00000146

The management system of

Prosum Medical Ltd

Unit 14 Cowley Mill Road Uxbridge UB8 2DB United Kingdom
has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products

Annex V:

Blood Collecting needles,

Dental needles,

Extension sets,

Hypodermic needles,

IV Catheters,

Infusion sets,

Insulin pen Needles,

Scalp vein sets,

Sterile syringes for use with needles,

Syringes for insulin

Class I sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Irrigation syringes,

Dispensing Hypodermic Needles (Blunt Fill Needles),

Sterile syringes for use without needles.

Where the above scope includes class IIb or class III medical device(s), a valid Type Examination Certificate according to Annex III [as modified by Part 2 of Schedule 2A to The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on following reports: GB/PC/240852

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 20 March 2024 until 20 March 2029 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 24 March 2023



Authorised by

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