EC Certificate Production Quality Assurance System: Certificate GB12/84913

The management system of

Medicina Ltd

Unit 1-4 Rivington View Business Park, Station Road,
Blackrod, Bolton, BL6 5BN, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 October 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 May 2022
Issue 24. Certified since 01 February 2012

Certification is based on reports numbered GB/PC 223887

Authorised by

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Medicina Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 24

Detailed Scope

**Sterile (disposable) and non sterile (reusable)
Oral Tip and Enteral Syringes (without needles)**

**Sterile (disposable) and non sterile (reusable)
ENFit Enteral Syringe (without needles).**

Sterile disposable luer lock and luer slip intravenous syringes (without needle) and sterile disposable luer lock and luer slip intravenous insulin syringes (without needle).

**Sterile Silo Bag and Dressing for the treatment of Gastroschisis
Sterile ENFit Nasogastric Tubes for short term use.**

Annex V (sterility aspects only) - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

**Sterile disposable blunt fill and blunt fill filter needles
Sterile ACElok Ace Stopper Dressing**

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