ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 072344 0015 Rev. 00

Manufacturer:

Product Category(ies):

Infusion Sets for Single Use (with Needle),
Sterile Hypodermic Syringes for Single Use (with Needle),
Disposable Transfusion Set(with Needle),
Disposable Intravenous Needle,
Disposable Sterile Hypodermic Needle,
Sterile Auto-disable Safety Syringefor Single Use (with Needle),
Sterile Insulin Syringe for Single Use

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19587EXT01

Valid from: 2020-02-28
Valid until: 2024-05-26

Date, 2020-02-28

Dr. Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Perminov Andrei
Date: 2023.01.03 13:31:56 EET
Reason: MoldSign Signature
Location: Moldova