



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 098477 0002 Rev. 01

Manufacturer:

ALLE S.R.L.

Via XX Settembre, 74
46019 Viadana (MN)
ITALY

Facility(ies):

ALLE S.R.L.

Via Chizzalunga 1, 36066 Sandrigo (VI), ITALY

**Product
Category(ies):**

Infusion sets for pump and accessories (connectors, extension
lines).

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.:

ITA1422211

Valid from:

2020-02-17

Valid until:

2024-05-26

Date,

2020-02-17

Christoph Dicks
Head of Certification/Notified Body