



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 101488 0002 Rev. 00

Manufacturer

Nuline Limited

Doonview
Patna, Ayrshire KA6 7JW
UNITED KINGDOM

**Product
Category(ies):**

Sterile Surgical Gowns,
Sterile Surgical Drapes,
Sterile Drape Packs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 75943021

Valid from: 2020-03-18
Valid until: 2024-05-26

Date, 2020-03-18

Christoph Dicks
Head of Certification/Notified Body