





Product Service

Certificate

No. Q5 106770 0002 Rev. 00

Holder of Certificate: Metallform (Malta) Limited

HF 64 Hal Far Industrial Estate

3000 B'Bugia BBG

MALTA

Certification Mark:



Design and development, and production of non-active **Scope of Certificate:**

medical disposables for the administration of fluids, for

infusion and transfusion, and for drainage.

Design and development, and production of injection-molded components and subassemblies for non-active disposable medical devices for the

administration of fluids, for infusion and

transfusion, and for drainage.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 106770 0002 Rev. 00

Report No.: 713196752

Valid from: 2021-01-22 Valid until: 2023-04-27

Christoph Dicks 2021-01-22 Date,

Head of Certification/Notified Body



Certificate

No. Q5 106770 0002 Rev. 00

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Metallform (Malta) Limited

HF 64 Hal Far Industrial Estate, 3000 B'Bugia BBG, MALTA

Scope: Design and development, and production of non-active

medical disposables for the administration of fluids, for

infusion and transfusion, and for drainage.

Intensiv Medical Products IMPROMEDIFORM GmbH Gielster Stück 11, 58513 Lüdenscheid, GERMANY

Scope: Design and development, and production of non-active

medical disposables for the administration of fluids, for

infusion and transfusion, and for drainage.

MForm GmbH & Co. KG

Gielster Stück 11, 58513 Lüdenscheid, GERMANY

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Scope: Design and development, and production of injection-molded components and subassemblies for non-active disposable medical devices for the

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Parameters: ./.

