



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106138 0002 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb

Double J stent & set

Class IIa

PCN catheter & set

Ureteral catheter

Malecot catheter

Re-entry malecot catheter

Suprapubic catheter

Braided shaft catheter

Dual lumen catheter

Facial dilator

Amplatz dilator & set

Ureteral dilator & set

Ureteral balloon dilator

Double J stent & set

Mono J stent

Endopyelotomy stent

Guidewire

IP Needle

Chiba needle

Stone basket

Perk basket

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

Page 1 of 3

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Date, 2020-04-03

Christoph Dicks
Head of Certification/Notified Body

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