



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Christoph Miethke GmbH & Co. KG

Ulanenweg 2
14469 Potsdam
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and accessories for the treatment of hydrocephalus according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	009066 MR2
Certificate unique ID	170774587
Effective date	2021-03-05
Expiry date	2024-05-26
Frankfurt am Main	2021-03-05

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Device family	Device
TD 01 Shunt systems Class IIb	DUALSWITCH VALVE SHUNTASSISTANT SHUNTASSISTANT 2.0 paediGAV GAV GAV 2.0 proGAV proGAV 2.0 uniGAV miniNAV proSA M.blue M.blue plus
TD 02 Shunt system accessories Class IIb	Peritoneal Catheters Burrhole Reservoirs Burrhole Reservoir PEEK Prechamber Burrhole Deflectors Titanium Connectors Valve board
TD 03 Shunt system accessories Class III	Ventricular Catheters Lumbar Catheter Set
TD 04 Instruments Class Is	Check Mate
TD 05 Instruments Class Is	THOMALE GUIDE
TD 05 Instruments Class Im	THOMALE GUIDE Application
TD 06 Instruments Class IIa	Tunneler