



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

THI Total Healthcare Innovation GmbH

Gewerbestr. 4
9181 Feistritz im Rosental
Austria

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:

Sterile surgical drapes and sterile and non-sterile medical devices for osteosynthesis 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.	489169 MR2
Certificate unique ID	170689495
Effective date	2018-02-02
Expiry date	2023-02-01
Frankfurt am Main	2018-02-02

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	Class
Sterile surgical drapes	Sterile protection (Lens-Hood)	Is
	Sterile toga	Is
	SPS Sterile Protection Shield	Is
Sterile and non-sterile medical devices for osteosyntheses	Plates	IIb
	Screws	IIb
	Intramedullary nails	IIb
	Wires	IIb