EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Globus Medical, Inc.

Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA, 19403
United States of America

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:

Orthopaedic and Spinal Implants and related instruments as listed in the 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.	342462 MR2
Certificate unique ID	170767767
Effective date	2020-04-02
Expiry date	2024-05-26
Frankfurt am Main	2020-04-02

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.

411.20 Version 1.0

Annex to certificate
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Device family	Device	Class
Implantable Spinal Screw/Rod/Plate Stabilization Systems	Thoracolumbar Screw/Rod Systems	IIb
	Thoracolumbar Plate Systems	IIb
	Occipital Cervical Thoracic Screw/Rod Systems	IIb
	Cervical Plates Systems	IIb
Intervertebral Implants	Lumbar Intervertebral Spacers	IIb
	Cervical Intervertebral Spacers	IIb
Corpectomy Implants	Corpectomy Spacers	IIb
Interspinous Implants	Interspinous Stabilization System	IIb
	Spinous Process Fixation System	IIb
	Radiolucent Spacers	IIb
Artificial Discs	Lumbar Artificial Discs	IIb
	Cervical Artificial Discs	IIb
Laminoplasty Devices	Laminoplasty Systems (sterile)	IIb
Instruments	Minimal Access Retractor System	IIa
	Cannulas	IIa
	Working Ports	IIa
	Bone Access Needles	IIa
	Tips	IIa
	K-Wires	IIa
	Annulotomy Knives	IIa
	Disc Shims	IIa
	Trial Spacers	Im
	Depth Gauges	Im
	Depth Probes	Im
	Torque Wrenches	Im
	Sterile Surgical Instruments	IIa
	Interspinous Process Fixation Instruments	Im
	Balloon Dilation System	IIa
	Facet Fixation Instruments (single use)	IIa
	Bone Graft Harvesting System	IIa
	Surgical Navigation and Robot Accessories	IIa
	VCF (Vertebral Compression Fracture) Instruments	IIa

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Device family	Device	Class
Bone Void Filler	Bioabsorbable Bone Void Filler	III
	Bioglass Bone Void Filler	III
	Bioglass Bone Void Filler with Collagen	III
Facet Implants	Facet Replacement Systems	IIb
	Radiolucent Facet Replacement Systems	IIb
Sacroilliac Fixation Implants	Sacroilliac Fixation System	IIb
Vertebral Compression Fracture Implants	Vertebral Compression Fracture Systems	IIb
Bone Cements	Radiopaque Bone Cement	IIb
Trauma Implants	Fracture System Screws/Plates	IIb
	Bone Screws	IIb
	Bone Plates	IIb
	Compression Screws	IIb
	External Fixation System Parts	IIb
	Intramedullary Nails	IIb