



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

GLOBUS
MEDICAL

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	170739659
Effective date	2019-03-18
Expiry date	2022-12-04
Frankfurt am Main	2019-03-18

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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
Certificate registration No.: 342462 MR2
Certificate unique ID: 170739659
Effective date: 2019-03-18



Globus Medical, Inc.

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

Device family	Device	Class
Intervertebral Spacers	SUSTAIN® Posterior Lumbar Interbody Fusion (PLIF) SUSTAIN® Anterior Cervical Discectomy and Fusion (ACDF) SUSTAIN® Anterior Lumbar Interbody Fusion (ALIF) SUSTAIN® Transforaminal Lumbar Interbody Fusion (TLIF) SUSTAIN® -O Unilateral Lumbar Interbody Fusion (ULIF) PATRIOT® Lumbar Spacer (Constitution® PLIF, Continental® ALIF, TransContinental®, Signature® TLIF and TransContinental® M Spacers) PATRIOT® Cervical Spacers (Colonial® ACDF) INDEPENDENCE® Spacers COALITION® Spacers CALIBER® Spacer InterContinental® Plate Spacer RISE® Spacer LATIS™ Spacer MONUMENT™ Spacer ALTERA™ Spacer ELSA™ Spacer MAGNIFY® and MAGNIFY® -S Spacer	IIb
Thoracolumbar Screw / Rod Systems	PROTEX® Stabilization System REVERE® Stabilization System H-LINK® Integrated Rod CORRIDOR® Fixation System CORRIDOR® Transarticular Washer BEACON® Stabilization System BEACON® ML Spacer REVOLVE® Stabilization System ZYFUSE® Facet Fixation System TRANSITION® Stabilization System ZYFLEX™ Stabilization System REVLOK® Fenestrated Screw System SRX™ Stabilization System CREO® Stabilization System CREO® Fenestrated Screw System SILC™ Fixation System REFLECT® Scoliosis Correction System	IIb



Annex to certificate
Certificate registration No.: 342462 MR2
Certificate unique ID: 170739659
Effective date: 2019-03-18



Globus Medical, Inc.

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

Device family	Device	Class
Thoracolumbar Plate Systems	GATEWAY® Thoracolumbar Plate System CITADEL® Anterior Lumbar Plate System TRUSS® Thoracolumbar Plate System PLYMOUTH® Thoracolumbar Plate System VESALE™ Lumbar Plate System	IIb
Cervical Plates	ASSURE® Anterior Cervical Plate System PROVIDENCE™ Anterior Cervical Plate System VIP® Anterior Cervical Plate System XTEND® Anterior Cervical Plate System UNIFY™ Dynamic Anterior Cervical Plate System	IIb
Corpectomy Spacers	XPand® Corpectomy Spacer XPand® Radiolucent Corpectomy Spacer NIKO® Corpectomy Spacer FORTIFY® Corpectomy Spacers and FORTIFY® Integrated	IIb
Occipital Cervical Thoracic Screw / Rod Systems	PROTEX® –CT Occipito-Cervico-Thoracic Stabilization System ELLIPSE® Occipito-Cervico-Thoracic Spinal System ELLIPSE CAPITOL™ Screws QUARTEX® Occipito-Cervico-Thoracic Spinal System	IIb
Interspinous Devices	FLEXUS™ Interspinous Spacer RETAIN® Radiolucent Spacer RENEGADE™ Interspinous Spacer SP-FIX® Spinous Process Fixation System SP-FLEX™ Interspinous Stabilization System	IIb
Artificial Discs	SECURE® –C Cervical Artificial Disc SECURE® –CR Cervical Artificial Disc SECURE® –C3 Cervical Artificial Disc ORBIT™ Anterior Lumbar Disc ORBIT™ –R Anterior Lumbar Disc TRIUMPH® Lumbar Disc TRIUMPH® -R Lumbar Disc InOrbit™ Lateral Lumbar Disc	IIb



Annex to certificate
Certificate registration No.: 342462 MR2
Certificate unique ID: 170739659
Effective date: 2019-03-18



Globus Medical, Inc.

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

Device family	Device	Class
Laminoplasty	RELIEVE® Laminoplasty System CANOPY™ Laminoplasty System HAVEN™ Laminoplasty System	IIb
Instruments	MARST™ Minimal Access Retractor System - Cannulas, Working Ports, Bone Access Needles, Tips - K-Wires, Annulotomy Knives, Disc Shims MARST™ 3V Minimal Access Retractor System ZYFUSE® Facet Fixation System (single use) RETRIEVE® Universal Bone graft Harvesting System EXCELSIUS GPS Accessories	IIa
Instruments	Trial Spacers, Depth Gauges, Depth Probes, Torque Wrenches Sterile Instruments – General SP-Fix® Interspinous Process Fixation Instruments ALVUE™ Balloon Dilation System	Im IIa Im IIa
Bone Void Filler	MICROFUSE® SIGNIFY® Bioactive	III III
Facet Replacement	ACADIA® Facet Replacement System ACADIA® Radiolucent Facet Replacement System	IIb
Sacroiliac Fixation VCF	SI-LOK® Sacroiliac Fixation System AFFIRM® VCF System CONTAIN® VCF System SHIELD® VCF System	IIb IIa IIb IIb
Bone Cement	FORTRESS™ Radiopaque Bone Cement	IIb
Trauma Implants	ANTHEM™ Fracture System CAPTIVATE™ Compression Screws ARBOR™ External Fixation AUTOBAHN™ Nailing System	IIb IIb IIb IIb