EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Globus Medical, Inc.

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

that the design of the following device(s)

MicroFuse® Bone Void Filler

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 342462 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: GMCE-027 MicroFuse Bone Void Filler Rev G dated 2016-01-28

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_MicroFuse dated 2016-02-07

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	342462 MRA
Certificate unique ID	170641573
Effective date	2016-02-07
Expiry date	2021-02-06
Frankfurt am Main	2016-02-07

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.

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