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)

KINEX Bioactive

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-081 KINEX Bioactive Rev. A dated 2019-01-05

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

Examination report: 0_20_Globus_Medical_Kinex_EGA.docx dated 2020-04-02

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

Certificate registration no.	548262 MRA
Certificate unique ID	170767766
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.