EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

FMZ GmbH

Charles Darwin Ring 3a
18059 Rostock
Germany

that the design of the following device(s)

alphatech® dental implants sterile
Tube-Line VTPS-BONIT®
Tube-Line-BONITex®
Uni-Line-VTPS-BONIT®
Slim-Line® BONITex®

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. 204456 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:	alphatech® Technische Dokumentation Implantate Klasse IIb/III Rev.6 dated 2019-04-24 Further basis for the examination is referenced in the examination report and relating documents mentioned below.
Examination report:	411_18d_Produktauslegungspruefung alphatech 102019 rev01.docx dated 2019-11-18 The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	204456 MRA
Certificate unique ID	170758542
Effective date	2019-12-09
Expiry date	2024-05-26
Frankfurt am Main	2019-11-18

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.