



# EC Design Examination Certificate

## Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

### Balt USA, LLC.

29 Parker  
Irvine, CA, 92618  
United States of America

that the design of the following device(s)

### TITAN™ Catheter System

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. 496217 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** TF-0006 Rev. A\_Titan Catheter System.docx dated 2019-02-28

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

**Examination report:** 411\_18e\_Report\_TFR\_Sample\_Version 6.docx dated 2019-05-01

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

Certificate registration no. 543996 MRA

Certificate unique ID 170740097

Effective date 2019-05-01

Expiry date 2024-04-30

Frankfurt am Main 2019-05-01

### 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.