EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Balt Extrusion

10 rue de la Croix Vigneron
95160 Montmorency
France

that the design of the following device(s)

Spirales (SPI), Flow-Coils (SPIF), CIRRUS (FIB)

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. 513975 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: TF-04_SPI SPIF FIB Rev.08 Draft1 dated 2017-09-22

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

Examination report: 411_18e_Report_TFR_SPI SPIF FIB_V1 dated 2017-11-05

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

Certificate registration no.	536992 MRA
Certificate unique ID	170696843
Effective date	2017-12-01
Expiry date	2019-07-12
Frankfurt am Main	2017-11-12

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.