



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)

BALTACCI - Selective and Hyperselective Catheter

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. 531975 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: TF05_BALTACCI_rev6-ds.pdf dated 2017-06-08
TF05_BALTACCI Rev.7.0.docx dated 2018-05-17

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

Examination report: 411_18e-Report_TFR_Baltacci dated 2017-07-09
411_18e_Report_TFR_Baltacci V2 dated 2018-05-19

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

Certificate registration no. 534992 MRA

Certificate unique ID 170718050

Effective date 2018-05-19

Expiry date 2022-07-31

Frankfurt am Main 2018-05-19

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.