



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Degradable Solutions AG

Wagistrasse 23
8952 Schlieren
Switzerland

that the design of the following device(s)

calc-i-oss™ CLASSIC

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. 413344 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Produktakte calc-i-oss vom 27.10.2017

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

Examination report: 081238_Report_TFR_Calciooss vom 22.04.2018

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

Certificate registration no. 413344 MRA

Certificate unique ID 170711732

Effective date 2018-04-22

Expiry date 2023-04-21

Frankfurt am Main 2018-04-22

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.