



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Biovision GmbH

Am Vogelherd 52
98693 Ilmenau
Germany

that the design of the following device(s)

Bioresorbable Pin: LeadFIX[®]

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. 020807 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Tech_Dok_LeadFIX_v0_2 dated 2015-07-23

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

Examination report: 411_18d_Bericht_Produktaktenprüfung_LeadFix_V1 dated 2015-08-06

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

Certificate registration no. 310744 MRA

Certificate unique ID 170628077

Effective date 2015-08-06

Expiry date 2020-08-05

Frankfurt am Main 2015-08-06

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.