# EC Design Examination Certificate

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

This is to certify that the manufacturer

## KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

that the design of the following device(s)

**BioPlug® suture anchor**

in the following variants:
2870310 BP BioPlug® 3.5
2870411 BP BioPlug® 4.2
2870514 BP BioPlug® 5.2

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. 528525 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** Produktakte Bioplug Nahtanker 3 dated 2017-04-07

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

**Examination report:** 411_18d_Bericht_Produktprüfung Bioplug (2).docx dated 2017-05-18

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

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|---|---|
| Certificate registration no. | 528525 MRA |
| Certificate unique ID | 170694883 |
| Effective date | 2017-11-09 |
| Expiry date | 2022-05-19 |
| Frankfurt am Main | 2017-11-09 |

**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.**