



# EC Design Examination Certificate

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

This is to certify that the manufacturer

**KLS martin**  
GROUP

### Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1  
78532 Tuttlingen  
Germany

that the design of the following device(s)

#### Resorbable Implant System Resorb X

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. 210299 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** Doku Bioimplantate\_Rev3 2018-03

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

**Examination report:** 411\_18d\_Bericht\_Produktprüfung ResorbX dated 04.05.2018

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

Certificate registration no. 210299 MRA

Certificate unique ID 170712117

Effective date 2018-05-27

Expiry date 2023-05-26

Frankfurt am Main 2018-05-04

### 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](mailto: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.



**Annex to certificate**  
**Certificate registration No.: 210299 MRA**  
**Certificate unique ID: 170712117**  
**Effective date: 2018-05-27**



## **Gebrüder Martin GmbH & Co. KG**

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### **Device Family:**

### **Devices:**

Resorb x Meshes

Mesh 0,3mm  
Mesh 0,3mm Rx-G  
Mesh 0,6mm  
Mesh 0,6mm Rx-G  
Mesh 0,8mm  
Mesh 0,8mm Rx-G  
Mesh 1,0mm  
Mesh 1,0mm Rx-G  
Mesh 1,5mm  
Mesh 1,5mm Rx-G  
Mesh 2,0mm  
Foil 0,1mm  
Foil 0,2mm  
Foil 0,3mm  
Foil 0,6mm  
Foil 0,6mm Rx-G  
Foil 0,8mm  
Foil 0,8mm Rx-G  
Foil 1,0mm  
Foil 1,0mm Rx-G  
Membran 0,1mm  
Membran 0,2mm  
3D-pre-shaped Implants 0,1mm  
3D-pre-shaped Implants 0,2mm  
3D-pre-shaped Implants 0,3mm  
3D-pre-shaped Implants 1,0mm

Resorb x Plates

Plates 0,8mm  
Plates 1,0mm  
Plates Rx-G

Resorb x Screws

Screws 1,6mm  
Screws 2,1mm  
Screws 2,4mm

Resorb x Pins

SonicPins Rx 1,6mm  
SonicPins Rx 2,1mm  
SonicPins Rx-G 2,1mm  
SonicMicroPins Rx 1,6mm  
Suture Anchor Pins 2,1mm