



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

KLS martin
GROUP

Karl Leibinger Medizintechnik GmbH & Co. KG

Kolbinger Straße 10
78570 Mühlheim
Germany

that the design of the following device(s)

RESORB-X® - Resorbable Implant System
Resorb-X® - SonicWeld Spine - Resorbable Implant System

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. 071006 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Doku Bioimplanate_Rev4.1_sig - incl Anhang.pdf dated 2020-02-13

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

Examination report: KLM_EGA_Bericht_ProdunktprüfungResorbX dated 2020-03-16

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

Certificate registration no.	071006 MRA
Certificate unique ID	170766823
Effective date	2020-03-16
Expiry date	2024-05-26
Frankfurt am Main	2020-03-16

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.



Annex to certificate
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Device Family:

Resorb x Meshes

Devices:

3D preshaped Implants Rx 0,1mm
3D preshaped Implants RxC 0,1mm
Foil Rx 0,1mm
Foil RxC 0,1mm
Membran Rx 0,1mm
Membran RxC 0,1mm
3D preshaped Implants Rx 0,2mm
Foil Rx 0,2mm
Foil RxC 0,2mm
Membran Rx 0,2mm
Membran RxC 0,2mm
3D preshaped Implants Rx 0,3mm
3D preshaped Implants RxG 0,3mm
Foil Rx 0,3mm
Foil Spine Rx 0,3mm
Mesh Rx 0,3mm
Mesh RxC 0,3mm
Mesh RxG 0,3mm
Mesh Spine Rx 0,3mm
Mesh Spine RxG 0,3mm
3D preshaped Implants Rx 0,6mm
3D preshaped Implants RxG 0,6mm
Foil Rx 0,6mm
Foil RxG 0,6mm
Foil Spine Rx 0,6mm
Foil Spine xG 0,6mm
Mesh Rx 0,6mm
Mesh RxC 0,6mm
Mesh RxG 0,6mm
Mesh Spine Rx 0,6mm
Mesh Spine xG 0,6mm
Mesh Rx 0,8mm
Mesh RxC 0,8mm
Mesh RxG 0,8mm
Foil Rx 1,0mm
Foil RxG 1,0mm
Foil Spine Rx 1,0mm
Foil Spine XG 1,0mm
Mesh Rx 1,0mm
Mesh RxC 1,0mm
Mesh RxG 1,0mm
Mesh Spine Rx 1,0mm
Mesh Spine xG 1,0mm



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Device Family:

Devices:

Resorb x Meshes

3D preshaped Implants Rx 1,0mm
3D preshaped Implants RxG 1,0mm
3D preshaped Implants Spine Rx 1,0mm
Mesh Rx 1,5mm
Mesh RxG 1,5mm
Mesh Rx 2,0mm
Mesh RxG 2,0mm

Resorb x Plates

Plates Rx 0,3mm
Plates Rx 0,6mm
Plates RxG 0,6mm
Plates Rx 0,8mm
Plates RxC 0,8mm
Plates RxG 0,8mm
Plates Rx 1,0mm,
Plates RxC 1,0mm,
Plates RxG 1,0mm
Plates Spine Rx 1,0mm,
Plates Spine xG 1,0mm

Resorb x Screws

Screws 1,6mm Rx
Screws 2,1mm Rx
Screws 2,4mm Rx
Screws 3,2mm Rx
Screws 3,2mm RxC

Resorb x Pins

SonicMicro Pins 1,6mm Rx
SonicPin 1,6mm Rx
SonicPin 1,6mm RxC
SonicPin 2,1mm Rx
SonicPin 2,1mm RxC
SonicPin 2,1mm RxG
SonicPin 2,1mm, Spine xG
SonicPin 2.1mm, Spine Rx
SutureAnchor Pin 2,1mm Rx
SutureAnchor Pin 2,1mm Spine Rx