

Certificate

EC Design Examination Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.4 of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Medovent GmbH

Friedrich-Koenig-Str. 3, 55129 Mainz, Deutschland

ECM certifies that the design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.4 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

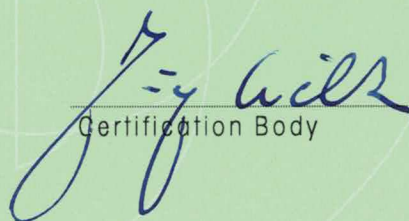
Any substantial changes of the examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number
767-281841

Registered under
Z/16/03952E

Valid until
October 16th, 2021

Aachen, October 17th, 2016


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zslg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/16/03952E

Page 1 of 1



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Non-active implantable products	Chitosan Nerve Guide -- Reaxon Nerve Guide: - RG321: Länge 30 mm, Durchmesser 2,1 mm - RG330: Länge 30 mm, Durchmesser 3 mm - RG340: Länge 30 mm, Durchmesser 4 mm - RG350: Länge 30 mm, Durchmesser 5 mm - RG360: Länge 30 mm, Durchmesser 6 mm -- Reaxon Direct: - RD121: Länge 14 mm, Durchmesser 2,1 mm - RD130: Länge 14 mm, Durchmesser 3 mm - RD140: Länge 14 mm, Durchmesser 4 mm - RD150: Länge 14 mm, Durchmesser 5 mm - RD160: Länge 14 mm, Durchmesser 6 mm	/

Special terms of validity:

None.

¹ UMDNS Code ist optional