

Certificate

Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical
Devices



ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

Laboratorium Dr. Deppe GmbH
Hooghe Weg 35; 47906 Kempen; Germany

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (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.

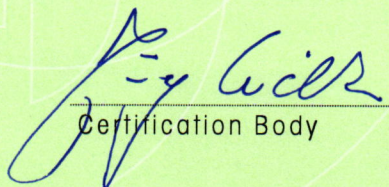
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number
128-15-217

Registered under
Z/15/03530E

Valid until
March 10th, 2020

Aachen, March 11th, 2015


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08



Benannt durch/Designated by
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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-240.10.12