

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

Helago-Pharma GmbH

An der Schleifmühle 2, 50374 Erftstadt, 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.

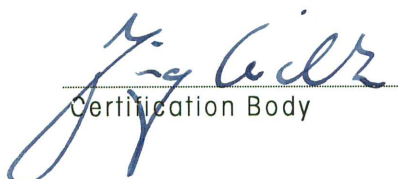
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number
327-16-922

Registered under
Z/16/03943E

Valid until
October 11th, 2021

Aachen, October 12th, 2016


Certification Body



Annex I of Certificate Z/16/03943E

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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
Single use devices	cleansing and disinfecting products for denture, braces and ear moulds	/

Special terms of validity:

None.