

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

Doceram Medical Ceramics GmbH

Hesslingsweg 65-67, 44309 Dortmund, 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.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

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

809-17-314

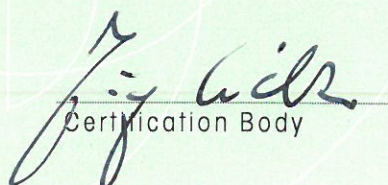
Registered under

Z/17/04066E

Valid until

April 26th, 2022

Aachen, April 27th, 2017


Certification Body



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

Annex I of Certificate Z/17/04066E
Page 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Dental Products	Restorative Materials, Dental, Crown/Bridge	16-723

Special terms of validity:

None.

Supplement to Annex I of Certificate Z/17/04066E
from June 29th, 2017
Page 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Dental Products	Zirconia Ceramics for Dental Restorations	/

Special terms of validity:

None.

Supplement to Annex I of Certificate Z/17/04066E
from December 14th 2017
Page 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Dental Products	coloring liquids	/

¹ UMDS Code is optional

Supplement to Annex I of Certificate Z/17/04066E
from February 1st 2019
Page 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Dental Products	Restorative Material Kits, Dental - Nacera Blend Tissue/Stain	16-732