

Certificate

Production Quality Assurance System Approval Annex V 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 V of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Laboratorium Dr. Deppe GmbH
Hoogheweg 35; 47906 Kempen, Germany

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by Annex V, section 4.

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 V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
128-17-516	Z/17/04088E	June, 10 th , 2022

Aachen, June 11th, 2017

Certification Body



SERTIFIKATAS

Produkcijos kokybės sistemos užtikrinimo patvirtinimas Medicinos prietaisų direktyvos Priedas V

ECM, Bismarckstr 106, 52066 Aachen šiuo liudija EC pagal 0481 ir šiuo deklaruoja, kad žemiau nurodytos kokybės užtikrinimo sistemos įvertinimas buvo atliktas vadovaujantis Direktyvos 93/42/EEC Priedo V reikalavimais.

Šis sertifikatas išduotas:

Gamintojas

Laboratorium Dr. Deppe

Hoogheweg 35, D-47906 Kempen Vokietija

ECM patvirtina, kad kokybės užtikrinimo sistema pagal kurią gaminami šiuo sertifikato I priede nurodyti produktai atitinka Direktyvos 93/42/EEC (skirtos medicinos prietaisams) Priedo V reikalavimus.

Šis sertifikatas galioja tik aukščiau nurodytiems produktams. Išskirtinės galiojimo sąlygos yra aprašytos šiuo sertifikato I priede.

Bet kokie esminiai kokybės užtikrinimo sistemos ar išvardintų produktų pakeitimai, galintys įtakoti atitiktį Direktyvos 93/42/EEC Priedui V yra atskiro vertinimo dalykas ir turi būti patvirtinti ECM.

Pranešimo numeris
128-17-516

Užregistruota
Z/17/04088E

Galioja iki
birželio 10, 2022

Aachen, birželio 11, 2017

(parašas)

Įgaliota įstaiga

Document to be presented to the health authorities of Lithuania

Declaration of Conformity (page 1 of 4)

and Guaranty of Quality and of Actual Usage of the products as such in Germany and elsewhere

Herewith we do declare that the products listed below are produced in accordance with the requirements of the directive 93/42/EEC, Annex II and V (Medical Devices Directive) and under control of the Quality Management System DIN EN ISO 9001:2008 and DIN EN 13485:2012.

The QM system is constantly being audited by our certifying body ECM (ECM, Zertifizierungsgesellschaft für Medizinprodukte GmbH, D-52068 Aachen, Germany, Tel: (0) 241 – 501034).

Products with the mark "CE 0481" are medical products of the class Ila or I Ib. Products with the mark "CE" are medical products of the class I. Products without CE mark are cosmetic products or cleansing products or biocides and are not comprised by the Medical Devices Directive.

All products have documented chemical and physical specifications. Only lots that fulfil completely their specifications are released for medical use in Germany and foreign countries.

Our company is known for decades as a manufacturer of its own trade mark medical disinfectants and skin care products, which are of course – as certified below – used as such in hospitals and other medical institutions.

Document to be presented in Lithuania

Declaration of Conformity (page 2 of 4)

List of Products	Name of Product	Type of Product
1.	Instru Plus Viruguard	Disinfectant concentrate for instruments; medical product of the class IIb, CE 0481
2.	Instru Plus Forte	Disinfectant concentrate for instruments; medical product of the class IIb, CE 0481
3.	Instru Plus O2	Disinfectant powder concentrate for instruments; medical product of the class IIb, CE 0481
4.	Instru Extra	Disinfectant concentrate for instruments; medical product of the class IIb, CE 0481
5.	Endo Star Neu	Disinfectant concentrate for instruments; medical product of the class IIb, CE 0481
6.	Instru Star	Disinfectant concentrate for instruments; medical product of the class IIb, CE 0481
7.	Instru Zym	Enzymatic detergent concentrate for instruments; medical product of the class I, CE
8.	Eco Zym	Enzymatic detergent concentrate for instruments; medical product of the class I, CE
9.	Instru Sol Forte	Alkaline detergent concentrate for instruments; medical product of the class I, CE
10.	Instru Suc	Disinfectant concentrate for dental suction tubes; medical product of the class IIb, CE 0481
11.	Alpha Guard GF	Ready to use disinfectant for surfaces and for immersing dental imprints; medical product of the class Ila, CE 0481

Document to be presented in Lithuania

Declaration of Conformity (page 3 of 4)

12. Endomat Plus Viruguard	- Disinfectant concentrate for instruments; mechanical use; medical product of the class IIb, CE 0481
13. Labomat E	- Enzymatic detergent concentrate for instruments; mechanical use; medical product of the class I, CE 0481
14. Labomat SPM	- Enzymatic detergent concentrate for instruments; mechanical use; medical product of the class I, CE 0481
15. Spray Off N	- Rapid surface disinfectant, ready-to-use; medical product of the class IIa, CE 0481
16. Spray Off Viruguard	- Rapid surface disinfectant, ready-to-use; medical device of the class IIa, CE 0481
17. Top Off	- Disinfectant wipes for surfaces; medical product of the class IIa, CE 0481
18. Delta Guard	- Surface disinfectant concentrate; medical product of the class IIa; CE 0481
19. Alpha Guard	- Surface disinfectant concentrate; medical product of the class IIa; CE 0481
20. Beta Guard	- Surface disinfectant concentrate; medical product of the class IIa; CE 0481
21. Op Derm Medical	- Ready-to-use skin disinfectant; biocide /

Document to be presented in Lithuania

Declaration of Conformity (page 4 of 4)

22. Op Sept Basic	- Ready-to-use hand disinfectant; biocide
23. Lotion Sept Gel	- Ready-to-use hygienic hand gel; cosmetic
24. Lotion Derm	- Ready-to-use body cleaning spray lotion; cosmetic
25. Lotion Med	- Ready-to-use, hygienic hand and body wash lotion; cosmetic
26. Lotion Med Scrub	- Ready-to-use, MRSA effective hygienic hand and body wash lotion; cosmetic
27. Lotion HD Neu	- Ready-to-use hand decontaminant; biocide
28. Spray Off Viruguard Wipes	- Ready-to-use disinfecting wipes; medical product of the class IIa, CE 0481
29. Top Off Alpha	- Disinfectant wipes for surfaces; medical product of the class IIa, CE 0481
30. Op Sept Classic	- Ready-to-use hand disinfectant; biocide
31. Alpha Guard GF Sensitive Wipes	- Disinfectant wipes for surfaces; medical product of the class IIa; CE 0481
32. Top Off XXL Wipes	- Disinfectant wipes for surfaces; medical product of the class IIa; CE 0481

D-47906 Kempen, the 2nd of March 2018

Lina Bartsch
Dr. Lina Bartsch
Laboratorium Quality Affairs Manager