

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 undermentioned 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

THEO Manufacturing BV
Sleperweg 44, 6222 NK Maastricht, The Netherlands

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

168-19-27

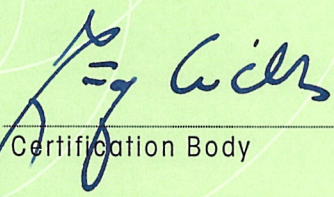
Registered under

Z/20/04664E

Valid until

June 24th, 2023

Valid as of: February 14th, 2020


Certification Body



Annex I of Certificate Z/20/04664E

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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 device	Dressings, Other	15-216

Special terms of validity:

None.