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 undermentioned 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

SanoMed Manufacturing B.V.

Transportweg 13 001, 4501PS Oostburg, The Netherlands

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
316-18-75	**Z/18/04272E**	**July 30th, 2023**

Valid as of: July 31st, 2018

Certification Body

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

Annex I to Certificate Z/18/04272E

Number of Pages: 1 of 1

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[1]
Single use products	- SanoSkin Melloxy	/
Single use products	- SanoSkin Melladerm PLUS - Epid-Zone Honey	/
Single use products	- SanoSkin OXY - Epid-Zone OXY - NeoMycolog Gel	/
Single use products	- SanoSkin Melladerm Tulle - Epid-Zone Honey Tulle	/
Single use products	- SanoSkin Cleanser	/
Single use products	- SanoSkin NET	/

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.

[1] UMDNS Code is optional