



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
1354GB451241023

Final assessment report no.
1354AU29F

Effective date
2024-10-23

Expiry date
2027-10-19

This is to certify that the management system of

MedSkin Solutions Dr. Suwelack AG

MedSkin Solutions Dr. Suwelack AG, Josef-Suwelack-Straße 2, 48727 Billerbeck, Germany

Facility ID: F005734

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

ISO 13485:2016 and the following country-specific requirements

- Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
- Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
- Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
- Japan: MHLW Ministerial Ordinance No. 169 as amended by MHLW Ordinance No. 128, Articles 4 to 68 PMD Act
- United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2024-10-23

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation


Lorenz Runge
Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
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Certificate no.: [1354GB451241023](#)
Place and date: [Hamburg, 2024-10-23](#)

Activities and products/services covered by this certificate

Design and development, manufacture and distribution of

- Medical devices for
 - Dermal substitutes
 - Wound care
 - Hemostasis

Sites covered by this certificate

MedSkin Solutions Dr. Suwelack AG, Josef-Suwelack-Straße 2, 48727 Billerbeck, Germany
Facility ID: F005734

Site-specific scope

Design and development, manufacture and distribution of

- Medical devices for
 - Dermal substitutes
 - Wound care
 - Hemostasis

MedSkin Solutions Dr. Suwelack AG, Fuhlentwiete 14, 20355 Hamburg, Germany
Facility ID: F007734

Site-specific scope

Distribution of

- Medical devices for
 - Dermal substitutes
 - Wound care
 - Hemostasis