

# Certificate

## The Auditing Organization

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**MedSkin Solutions Dr. Suwelack AG  
Josef-Suwelack-Strasse 2  
48727 Billerbeck  
Germany**

**Facility ID: F005734**

has introduced, applies and maintains a quality management system in the area of:

### **Design and development, manufacture and distribution of**

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

The compliance of this quality management system with the requirements of the below mentioned standard and country-specific regulatory requirements was verified by an audit:

## **ISO 13485:2016**

<b>Australia</b>	Therapeutic Good (Medical Devices) Regulations 2002, Schedule 3 Part 1 (excluding Part 1.6)
<b>Brazil</b>	RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009
<b>Canada</b>	Medical Devices Regulations SOR/98-282, Part 1
<b>USA</b>	21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D) ; 21 CFR 820

This certification is subject to surveillance by MEDCERT.

**Effective date: 2021-10-20**  
**Expiry date: 2024-10-19**

Report No.: 1354FS25F  
Process No.: QS - 1354  
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Hamburg, 2021-10-12

  
MEDCERT Certification Body  
Lorenz Runge

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT is an MDSAP authorised auditing organization  
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