

Certificate of Compliance EN ISO 13485

Scope of Attestation: Technical Cooperation Program between EU MDR Notified Body Partners and R.O.C. DOH Designated Medical Device GMP Auditing Organizations

Type of audit: Full Surveillance Audit, Initial Audit, Partial Surveillance Audit

Standard / Date of issue: PAA (Taiwan) / 2025-12-16

Audit date(s) (on site): 2025-09-23 - 2025-09-24

Manufacturer / Applicant: Speed Care Mineral GmbH
Street / P.O. Box: Genzkower Straße 7
Post code / City: 17034 Neubrandenburg
Germany

Customer number: QS-20359

Lead Auditor / Auditor: C. Tauer/ T. Greiner

Scope of Medical Devices to be exported to Taiwan R.O.C.:

- Design and development, manufacturing, and distribution of
 - Wound dressings
- Speed Care Mineral GmbH, Genzkower Straße 7, 17034 Neubrandenburg, Germany
 - Oversight of matters related to the management process
- Speed Care Mineral GmbH, Dahlienstraße 22 A, 23795 Bad Segeberg, Germany
 - Manufacturing of
 - Wound dressings
- Speed Care Mineral GmbH, Halenreihe 42, 22359 Hamburg, Germany
 - Design and development, manufacturing, and distribution of
 - Wound dressings

Existing certification acc. to: PAA (Taiwan)

Valid until: 2028-09-23

Attachments: (X) Confidential Report of the last certification audit: 20359AU04B
(X) Confidential most recent Delta Audit Questionnaire: 20359AU04TCPR

Declaration

DNV MEDCERT GmbH hereby declares that the attached documents referenced above are a copy of the original reports in its current revision and are identical to the reports issued to the manufacturer by DNV MEDCERT GmbH. This declaration is valid until the next audit.

Hamburg, Germany 2025-12-16



Representative responsible for certification,
DNV MEDCERT GmbH