

 Speed Care Mineral Life Saving Hemostasis Technology	Form Declaration of Conformity MDR (EU) 2017/745	Page 1 of 1 FB 07.03.02.01 Revision 00 Valid from 25.10.2022
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Declaration of Conformity

We

Speed Care Mineral GmbH
Genzkower Straße 7
17034 Neubrandenburg/Germany

SRN: DE-MF-000020226

are issuing this Declaration of Conformity under our sole responsibility. We declare that the medical device

Device (Trade names): SpeedM (REF: CG01E, CG01DE)

identical products with different trade names:

- **HARTMANN TRAUMA HEMOSTATIC DRESSING (REF: 831480)**
- **nextRESCUE SpeedM (REF: NR03-XHGF-SM-01)**

Intended purpose: SpeedM, HARTMANN TRAUMA HEMOSTATIC DRESSING and Next Rescue SpeedM are emergency hemostatic dressings intended for temporary treatment of heavily bleeding traumatic wounds. The product is suitable for all patients to whom the intended purpose can be applied. The product is not suitable for children under 6 years of age.

BASIC UDI-DI: 426237786SCM001AT

EMDN code: M040599

Nomenclature term: Haemostatic Dressings - Other

classified as Risk Class IIa, Rule no. 4 and 7, Annex VIII, chapter III
Performed Conformity assessment procedure: Annex IX

is in conformity with all applicable provision of the MEDICAL DEVICE REGULATION (EU) 2017/745 and meets the General Safety and Performance Requirements according to Annex I of this Regulation.

Name of Notified Body: DNV Medcert GmbH; Pilatuspool 2, 20335 Hamburg, Germany
Notified Body Number: 0482
EC certificate number: 20359GB448241002

Valid until: 2028-08-23

Signed for on behalf of

Hamburg, 2026-08-26
City, date



Signature (Ulf Pommerening, CEO)

Rev00 Declaration of Conformity SpeedM V3

2024-10-07

Final Audit Report

2026-08-27

Created:	2026-08-27
By:	Kerstin Lindae (kl@speedcaremineral.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA1YkqEYuaH62ePolVW9hbGkuFU2wuhP3u

"Rev00 Declaration of Conformity SpeedM V3 2024-10-07" History

-  Document created by Kerstin Lindae (kl@speedcaremineral.com)
2026-08-27 - 7:35:15 AM GMT
-  Document emailed to Ulf Pommerening (up@speedcaremineral.com) for signature
2026-08-27 - 7:35:18 AM GMT
-  Email viewed by Ulf Pommerening (up@speedcaremineral.com)
2026-08-27 - 10:52:44 AM GMT
-  Document e-signed by Ulf Pommerening (up@speedcaremineral.com)
Signature Date: 2026-08-27 - 10:53:02 AM GMT - Time Source: server - Signature Appearance Selected: IMAGE
-  Agreement completed.
2026-08-27 - 10:53:02 AM GMT