

We,

BSN Medical SAS
1 rue du Millenaire
72320 VIBRAYE
France
(SRN: FR-MF-000000598)

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Specialist® E

Basic UDI-DI:

4042809400419369B

Intended purpose:

Pre-cut splints are for external rigid immobilization through splinting procedures in all clinical situations judged suitable by qualified healthcare professionals.

Plaster of Paris is intended for all kind of plaster cast for orthopaedic and traumatology.

Conformity assessment route: **Annex II+III**

Classification rule:

1

Classification:

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The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Declaration of conformity issued: 21.10.2024

Compiled and released:

VIBRAYE, 21.10.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
72259-00000-04	SPECIALIST E SLAB 10CM X 20M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72259-00
72259-00001-04	SPECIALIST E SLAB 12.5CM X 20M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72259-01
72259-00002-04	SPECIALIST E SLAB 15CM X 20M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72259-02
72259-00003-04	SPECIALIST E SLAB 20CM X 20M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72259-03