

We,

BSN Medical SAS
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France
(SRN: FR-MF-000000598)

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

Product Name:

Gypsona®

Basic UDI-DI:

4042809400349099J

Intended purpose:

Plaster of Paris bandages are for external rigid immobilization through casting 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: **I**

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.

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BSN Medical SAS

Article	Description	REF
71985-00000-01	GYPSONA 10CM X 2.7M WHITE 48 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-00
71985-00001-01	GYPSONA 12.5CM X 2.7M 24 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-01
71985-00002-01	GYPSONA 15CM X 2.7M WHITE 24 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-02
71985-00003-01	GYPSONA 20CM X 2.7M WHITE 24 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-03
71985-00004-01	GYPSONA 5CM X 2.7M WHITE 48 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-04
71985-00005-01	GYPSONA 7.5CM X 2.7M WHITE 48 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-05
71985-00006-01	GYPSONA 10CM X 2M 40 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-06
71985-00007-01	GYPSONA 12.5CM X 2M 20 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-07
71985-00008-01	GYPSONA 15CM X 2M 20 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-08
71985-00012-01	GYPSONA 20CM X 2M 20 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-12
71985-00013-01	GYPSONA 5CM X 2M 40 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-13
71985-00014-01	GYPSONA 7.5CM X 2M WHITE 40 EN DE FR ES IT NL PT SV NO DA FI ET AR ZH	71985-14