EU DECLARATION OF CONFORMITY

REGULATION ON MEDICAL DEVICES (EU) 2017/745, ANNEX IV

NORGESPLASTER AS

SRN: NO-MF-000022061

This EU Declaration of Conformity is issued under the sole responsibility of Norgesplaster AS.

We hereby declare that the Medical Device products listed below conform to the Regulation on Medical Devices (EU) 2017/745.

Our Quality System and devices of higher risk classes are verified by Notified Body, DnV No 2460 Conformity assessment ; The TF 1.4 comply with the General Safety and Performance Requirements of Annex I due to MDR. Classification, Rule 4, Annex VIII due to MDR.

Basic UDI-DI: 7022750014005C

EMDN (CND) code: M04010101 **GMDN code:** 34864

Risk class: I

Intended use:
Askina Soft: Protect injury with a plaster/woundpad. Used for cuts, grazes wounds, burn wounds and other skin damages/disorders which needs to be covered.

Article number	BBraun article number	Name	Label
4015	9086030	Askina Soft Unsterile 4cmx5m	BBraun
4016	9086048	Askina Soft Unsterile 6cmx5m	BBraun
4017	9086056	Askina Soft Unsterile 8cmx5m	BBraun

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Effective

Common Specifications applied: No applicable CS available

Vennesla,v5, 2022-04-08

Kristin Sannes
Regulatory Affairs and Quality Manager
Person Responsible for Regulatory Compliance
Norgesplaster AS

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