DECLARATION OF CONFORMITY

Manufacturer: NORGESPLASTER A.S. Granlivegen 21, 4707 Vennesla, Norway

Medical Devices:

BBraun article	Basic UDI-DI (GMN)	Product description
9086030	7022750014005C	Askina Soft unsteril
9086048	7022750014005C	Askina Soft unsteril
9086056	7022750014005C	Askina Soft unsterile

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

Classification : Class I, non sterile , Rule 4, Annex VIII Directive MDR 2017/745/EU.

Conformity assessment: Norgesplaster declare that the technical file of these devices comply with the Essential Requirements of Annex I in the MDR 2017/745/EU.

Notified Body for our Quality System and higher risk classes:

DnV GL Presafe, No: 2460. Adress : Veritasveien 3, N-1363 Høvik, Norway

ISO 13485:2016/NS-EN ISO 13485:2016;Certificate number 243069-2017-Aq_NOR_NA_PS Rev 1.0

Technical standards which the devices are in compliance with;

- **EN ISO 13485:2016**
- **EN ISO 14971: 2012 (2019)**
- **EN ISO 15223-1:2016, corr ver 2017-03**
- **EN 1041:2008 + A1-2013**
- **EN ISO 10993-1:2010 + EC 1-2010 (2018)**

Vennesla, 20.05.2021

Quality Manager/ Regulatory Affairs

Effective

Norgesplaster AS
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