NASARA CORPORATION
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Chapter IV. EU Declaration of Conformity

EC Declaration of Conformity

Certificate No : NSR40 DOC-210503

We herewith declare that the under-mentioned products are in conformity with the general safety and performance requirements and provisions of Regulation (EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Product Name: Cross Tape
Model Name: NASARA Gitter Tape

SRN: KR-MF-000012755
Basic UDI-DI: 8809651910003AR

Classification: Class I (Regulation (EU) 2017/745 on medical devices Annex VIII Rule 1 is Class I)

Conformity Assessment Route : Annex IX, Regulation (EU) 2017/745 on medical devices

Applied Standard: EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15223-1:2016, EN 1041:2008 /A1:2013, EN 62366-1:2015+A1:2020, IEC62321:2008, IEC TR 62366-2:2016, MEDDEV 2.7/1 Rev.4, MEDDEV 2.12/1 Rev.8, MEDDEV 2.12/2 Rev.2

Manufacture: Nasara Corporation

EC Representative: MIKROS GmbH (SRN: DE-AR000005914)
Meiendorfer Mühlenweg 21, D-22393, Hamburg

GMDN Code No.: 33521 [Bandage/tape, adhesive]
EMDN Code No. : M030403 [FUNCTIONAL BANDAGES WITH ANELASTIC TAPES]

CE

Place of Issue: Paju-si, Gyeonggi-do, Korea

Signature :

Date of Issue: 2021.05.03

Chang lim Kim/ President
Nasara Corporation