

MANUFACTURER:



Weaver and Company
565 Nucla Way, Unit B
Aurora, Colorado 80011
United States of America
+1 800 525 2130

SRN: T.B.D.

AUTHORIZED REPRESENTATIVE:



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
+31 70 345 8570

SRN: NL-AR-000000116

This declaration of conformity is issued under the sole responsibility of the Manufacturer.

Products: Nuprep® Skin Prep Gel

Intended purposes: For use when a lower skin impedance would enhance test results, e.g.: EEG exams, evoked potential procedures, ECG stress tests, cardiac rehabilitation monitoring, and cardiac catheter monitoring exam procedures.

Ten20® Conductive Paste

Intended purposes: For use in neuromonitoring procedures in conjunction with non-gelled neurodiagnostic electrodes, e.g.: EEG exams, evoked potential procedures, PSG, and MSLT.

Models: See Page 2

UDI-DI: See Page 2

The medical devices described on this Declaration:

- Are in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices ("EU MDR"), as amended from time to time;
- Are Class I devices according to the criteria of Regulation 2017/745 Annex VIII, Rule 1;
- Are non-invasive medical devices not intended as sterile devices;
- Do not perform a measuring function;
- Are not reusable surgical instruments;
- Are therefore eligible for, and conform with, the conformity assessment route described in Article 52(7) of the EU MDR, as carried out by the Manufacturer;
- Do not require the intervention of a Notified Body, per applicable legislation;
- Meet the General Safety and Performance Requirements of Annex I of the EU MDR; and
- No Common Specifications were used in relation to this Declaration.

The initial date of the CE Mark on Nuprep Skin Prep Gel and Ten20 Conductive Paste was June 1, 1998.

Signed for and on behalf of Weaver and Company:

Printed Name: Nicholas W. Lee
Title: Regulatory Compliance Manager

Place of Issue: Aurora, CO USA

Date of Issue: 2021-05-25

Expiration Date: 2022-05-24

This Declaration applies to the following models:

Product/Model	UDI-DI (GMN)
Nuprep® Skin Prep Gel <ul style="list-style-type: none">▪ 4oz Tube 3-pack (#10-30)▪ 4oz Tube Kit (#10-30K)▪ 25g Tube Sample (#10-25S)▪ 25g Tube Kit (#10-25)▪ 25g Tube 6-pack (#10-61)▪ 25g Tube 20-pack (#10-65)	08918930021030SV
Ten20® Conductive Paste <ul style="list-style-type: none">▪ 4oz Jar 3-pack (#10-20-4)▪ 8oz Jar 3-pack (#10-20-8)▪ 4oz Tube 3-pack (#10-20-4T)▪ 4oz Tube Kit (#10-20-4TK)▪ 50g Jar Sample (#10-20-2S)▪ 50g Jar 3-pack (#10-20-2)▪ Single-Use Cup 24-pack (#10-20-1)▪ Single-Use Cup 3-pack (#10-20-1S)	08918930021020SS