SUBLIMED

MDR Declaration of conformity

The manufacturer,

SUBLIMED SAS, 137 Rue de Mayoussard, 38430 Moirans, France

With the single registration number (SRN): FR-MF-000007546

Guarantees and declares, under our sole responsibility, that the:

- **Transcutaneous Electrical Nerve Stimulator named VitaliTENS (8703703)** class IIa Medical device,
- **VitaliTENS Mobile Apps** (EXP2AA100, EXP2AA200) class IIa Medical device,

With EMDN code: Z120622

With Basic UDI-DI: 3770018808SBMTENSAPPNU

Comply with the applicable requirements of Regulation 2017/745, amended by Regulation 2020/561, according to Annex IX chapters I and III.

This statement is based on the following:

- EC certificate **MDR 760779** of full Quality Assurance System issued by the BSI (2797)
- Quality Management System -ISO 13485 : 2016 certificate: **MD 654973**

Identification of the critical subcontractors' manufacturing site:

MAATEL, 259 rue du Rocher de Lorzier, 38430 Moirans, France

STIPLASTICS MEDICAL PHARMA, 62 Chemin des Plantées 38160 Saint Marcellin, France

First issued of EC mark: 2018-01-23

This for the duration of the validity of the certificate, i.e. until: 2028-06-06

President (CEO)

SUBLIMED
137, rue Mayoussard
38430 Moirans - France
SIRET 81395901200028

Signature (date, place) :

Nicolas Maurice Joseph Alphonse KARST

Signature numérique de Nicolas Maurice Joseph Alphonse KARST
Date : 2023.06.09 15:13:57 +02'00'