

Manufacturer,

**MDB TEXINOV**  
**56 Route de Ferrossière**  
**38110 Saint Didier de la tour**  
**France**  
**SRN : FR -MF-000001728**

Ensure and declare, under our sole responsibility, that the medical device :

- **FLUXMEDICARE V2**

is a medical device of class IIa and complies with the requirements of the regulation 2017/745 annex IX chapter I and III ,Basic UDI-DI : 3770021816LIGHTSOURCE9J

The FLUXMEDICARE® V2 is a device intended to be used solely for photodynamic therapy (PDT) for the treatment of skin lesions.

- MDB TEXINOV commits to fulfil its obligations relative to the approved quality management system;
- MDB TEXINOV commits to supervise the suitability and the efficiency of the quality management system ;
- MDB TEXINOV commits to put in place and to keep up to date a procedure for collecting all the data acquired on the medical device from production and implement appropriate means for corrective actions;
- MDB TEXINOV commits to inform the relevant authorities of all the following events as soon as we are aware :
  - i) all failure or damage of properties and/or performance of a device and any inadequate labelling or mismatching in the leaflet likely to cause or to have caused the death or a serious deterioration in the patient or user health status;
  - ii) all reason from a technical or medical aspect linked to properties or performances of a device and that have caused ,for the reasons listed point i), the systematic recall by ourselves of all devices belonging to the same type.
- MDB TEXINOV confirms that medical device FLUXMEDICARE V2 doesn't contain pharmaceutical substance, substance from animal or human origin and carcinogen, mutagen or reprotoxic substance.

This device is covered by CE certificate : MDR 777469 by notified body : **BSI** (notified body identifier: 2797), Say Building ,John M .Keynesplein 9, 1066 EP AMSTERDAM ,The Netherlands under the conformity assessment procedure MDR 2017/745, annex IX, chapter I and III. In addition, this device complies with Directive 2011/65/UE, DIRECTIVE 2006/42/CE

First year of obtaining CE marking: **2024-10-17**

Current date of the latest certificate version: **2024-10-17**

Certificate expiration date: **2029-10-16**

Name and function : Jacques TANKÉRE

Location : 56 route de Ferrossière, 38110 Saint-Didier-de-la-Tour - FRANCE

Date : 18 octobre 2024

