

The manufacturer,

**MDB TEXINOV**  
**56 route de la Ferrossière**  
**38110 Saint Didier de la Tour**  
**FRANCE**  
**SRN : FR-MF-000001728**

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

**TEXISHIELD (REF F2-B IIR) Mask FFP2 NR D Type IIR**

is a medical device of class I and complies with the requirements of the regulation 2017/745

Code CND : T020601 Standard surgical face mask  
Basic UDI-DI 3770021816MASQUESHF

- 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 TEXISHIELD IIR doesn't contain pharmaceutical substance, substance from animal or human origin and carcinogen, mutagen or reprotoxic substance.

**MDB TEXINOV** markets class I medical devices under the self-certification regime according to the requirements of regulation 2017/745.

Fisrt year of CE Marking : **2021**

Name and fonction : TANKERE Jacques-PDG

Done at : 15 février 2022

Date :





Référence	Description	Photographie
<p><b>TEXISHIEL D (Réf F2- B IIR)</b></p>	<p>Mask FFP2 NR D et surgical face mask IIR selon EN149 : 2001 + A1 : 2009 et EN 14683 :2019+AC :2019</p>	