



## Declaration of Conformity

<b>Manufacturer's Name:</b>	PMS Tibbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş.
<b>Manufacturer's Address:</b>	Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz, 33020 Mersin/TURKEY Phone: +90 324 238 7042 Fax : +90 324 238 6549 e-mail : pms@pmsmedikal.com
<b>SRN (Single Registration Number):</b>	TR-MF-000016263
<b>Basic UDI-DI:</b>	86989733PMS2021BR
<b>Name of the Devices:</b>	Crepe Paper (Standard, Soft, Nonwoven) SMS, SMMS Sterilization Wraps
<b>Product codes:</b>	WP...(Standard Crepe, SWP ...(Soft Crepe), NOW...(Nonwoven) SMSL, SMSH
<b>Brand Name:</b>	PMSSteripack
<b>Classification:</b>	Class I, (EU) 2017/745 MDR- Annex VIII, Rule 1
<b>Related Standards:</b>	EN 868-2:2017, ISO 11607-1, ISO 11140-1, ISO 13485:2016,
<b>Notified Body Address:</b>	N/A
<b>Notified Body Identification number:</b>	N/A
<b>Conformity Assessment Route:</b>	Annex II (Technical Documentation) and Annex III (Technical documentation on post-market surveillance)



This declaration of conformity is under the sole responsibility of PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş. and issued as per Annex IV of (EU) 2017/745 MDR.

We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Lloyd's Register Quality Assurance Limited.

All supporting documentation is retained at the premises of the manufacturer.

**Signed for and on behalf of PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş.**

**Authority :** Taner ERSEN

**Function :** Quality Assurance Manager

**Date :** January 03, 2022

**Place :** Mersin-Turkey

