

# DECLARATION of CONFORMITY E.U.

(According to Regulation (EU) 2017/745)

**We manufacturer solely responsible for declaring that the Medical Devices mentioned in this statement are of Low-Risk Class**

**(Class I, Classification according to annex VIII of the Council Regulation (EU) 2017/745) and comply with the requirements of the European Regulation 2017/745 and where appropriate, the standards and legislation referred to.**

MANUFACTURER:	<b>G. BOURNAS &amp; ST. BOURNA Co.</b>
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REF. CODE	PRODUCT DESCRIPTION	INTENDED USE	UDI-DI	RULE
108.082.B	Soft Care Dental Bibs with dispenser - Light Blue	Its purpose is to protect patient's clothing from liquids during medical examination	5208107001738	1
108.025.SB	Soft Care Premium Standard 2ply Paper & PE Examination Roll 58cm x 50m - Light blue	Its purpose is to protect patient's clothing from liquids during medical examination	5208107007884	1
109.083W	Soft Care Dental Bibs Soft Care Standard - White	Its purpose is to protect patient's clothing from liquids during medical examination	5208107008768	1
108.035.SAM150	Soft Care Supreme Standard 1ply Non-woven Examination Roll 58cm x 150m - white	Its purpose is to protect patient's clothing from liquids during medical examination	5208107013632	1
108.035.SD.BL	Soft Care SUPREME PLUS Non woven roll Black 20gr - 58cm x 70m	Its purpose is to protect patient's clothing from liquids during medical examination	5208107008447	1

**APPLIED STANDARDS & LEGAL REQUIREMENTS**

ISO 13485:2016

**APPROVAL**



<b>NAME:</b>	Prili Antigony
<b>POSITION:</b>	Quality Assurance Director
<b>PLACE:</b>	Attica Athens
<b>DATE:</b>	<b>30.01.2024</b>
<b>SIGN:</b>	<p>             GEORGE BOURNAS &amp; STAVROULA BOURNA C.O.            "BOURNAS MEDICALS"            MEDICAL &amp; HOSPITAL PRODUCTS            XRISIIDOS 87, ILLION 13122            BRANCH: STABO 18, 14564 KIFISIA            TEL: +302102622568 - FAX: +302102612089            VAT NUMBER: EL 099067902            LOCAL REVENUE (TAXATION) OFFICE: AG. ANARGIRON         </p>