



## DECLARATION of CONFORMITY E.U.

We are solely responsible for declaring that the Medical Devices mentioned in this statement are of Low-Risk Class (Class I) and comply with the requirements of the European Regulation 745/2017 and where appropriate, the standards and legislation referred to.

<b>MANUFACTURER:</b>	<b>BOURNAS MEDICALS</b>
<b>SRN:</b>	<b>GR-MF-000023099</b>
<b>ADDRESS:</b>	<b>18 Seneka Str, 14564 Kifisia, Athens, Greece</b>
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<b>WEB SITE:</b>	<b>www.bournas-medicals.gr</b>
<b>COMPETENT AUTHORITY:</b>	<b>National Organization of Medicines</b>
<b>CONTACT DETAILS:</b>	<b>Address: 284, Mesogeion Str 15562 Holargos, Athens Greece Telephone: +30 213 2040000 Web site: www.eof.gr</b>

### LIST OF PRODUCTS COVERED BY THIS DECLARATION

No	PRODUCT	CODE	UDI-DI	INTENDED USE	RULE
1.	Gloves nitrile Soft Touch Vivid White (100 pcs)	110.272	5208107000502	Protection of the Patient during medical examination	1
2.	Gloves nitrile Soft Touch Vivid Black (100 pcs)	110.273	5208107000519	Protection of the Patient during medical examination	1
3.	Gloves nitrile Soft Touch Vivid Blue(100 pcs)	110.274	5208107000526	Protection of the Patient during medical examination	1
4.	Gloves nitrile Soft Touch Vivid Purple (100 pcs)	110.277	5208107000557	Protection of the Patient during medical examination	1
5.	Gloves nitrile Soft Touch Vivid Orange (100 pcs)	110.276	5208107000540	Protection of the Patient during medical examination	1
6.	Gloves nitrile Soft Touch Vivid Green (100 pcs)	110.278	5208107000564	Protection of the Patient during medical examination	1
7.	Gloves nitrile Soft Touch Vivid Fuschia (100 pcs)	110.275	5208107000533	Protection of the Patient during medical examination	1
8.	Gloves nitrile Soft Touch Vivid	110.271	5208107000496	Protection of the	1

	Light Blue (100 pcs)			Patient during medical examination	
9.	Gloves nitrile Soft Touch Vivid Pink (100 pcs)	110.280	5208107000571	Protection of the Patient during medical examination	1
10.	Gloves nitrile Soft Touch Vivid Yellow(100 pcs)	110.281	5208107000588	Protection of the Patient during medical examination	1

**APPLIED STANDARDS & LEGAL REQUIREMENTS**

ISO 13485:2016



**APPROVAL**

<b>NAME:</b>	<b>Prili Antigony</b>
<b>POSITION:</b>	<b>Quality Assurance Director</b>
<b>PLACE:</b>	<b>Kifisia</b>
<b>DATE:</b>	<b>9/4/21</b>
<b>SIGN:</b>	<p>GEORGE BOURNAS &amp; STAVROULA BOURNA G.O.  "BOURNAS MEDICALS"  MEDICAL &amp; HOSPITAL PRODUCTS  KRISIIDOS (B7) ILLION 13122  BRANCH STASO 18, 14567 KIFISIA  TEL: +302102622966 FAX: +302102612089  VAT NUMBER: EL 999067902  LOCAL REVENUE (TAXATION) OFFICE: AG. ANARGIRON</p>