

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.

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| MANUFACTURER: | BOURNAS MEDICALS |
| SRN: | EL099067902 |
| ADDRESS: | 18 Seneka Str, 14564 Kifisia, Athens, Greece |
| E-MAIL: | info@bournas-medicals.gr |
| TELEPHONE: | +30 210 2622568 |
| WEB SITE: | www.bournas-medicals.gr |

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| COMPETENT AUTHORITY: | National Organization of Medicines |
| CONTACT DETAILS: | Address: 284, Mesogeion Str 15562 Holargos, Athens Greece Telephone: +30 213 2040000 Web site: www.eof.gr |

LIST OF PRODUCTS COVERED BY THIS DECLARATION

| No | PRODUCT | CODE | INTENDED USE | RULE |
|-----|--------------------------------------------------|------------|------------------------------------------------------|------|
| 1. | Elite thermal laminated examination roll | 108.02x.ST | Protection of the Patient during medical examination | 1 |
| 2. | Premium Laminated with glue examination roll | 108.02x.SA | Protection of the Patient during medical examination | 1 |
| 3. | Eco Laminated with glue examination roll | 108.02x.SE | Protection of the Patient during medical examination | 1 |
| 4. | Classic paper 2ply examination roll | 108.01x.Sx | Protection of the Patient during medical examination | 1 |
| 5. | Regular paper embossed 2ply examination roll | 108.01x.SG | Protection of the Patient during medical examination | 1 |
| 6. | Supreme Non-woven examination roll | 108.03x.xx | Protection of the Patient during medical examination | 1 |
| 7. | Prestige Non-woven + PE examination roll | 108.04x.x | Protection of the Patient during medical examination | 1 |
| 8. | Rainbow dental bib in sheets 2ply paper +1ply PE | 108.081 | Protection of the Patient during medical examination | 1 |
| 9. | Rainbow dental bib in sheets 1ply paper +1ply PE | 108.082 | Protection of the Patient during medical examination | 1 |
| 10. | Dental bibs on roll 30cm X 50m | 108.061 | Protection of the Patient during medical examination | 1 |
| 11. | Rainbow head rest cover | 109.201.x | Protection of the Patient during medical examination | 1 |

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|-----|------------------------------------------|-------------|------------------------------------------------------|---|
| 12. | Dental bibs on roll with neckline | 109.101.x | Protection of the Patient during medical examination | 1 |
| 13. | Rainbow tray Paper | 109.301.x | Protection of the Patient during medical examination | 1 |
| 14. | Hyper air laid wipes | 108.10x | Protection of the Patient during medical examination | 1 |
| 15. | Hyper air laid wipes in roll | 108.11x | Protection of the Patient during medical examination | 1 |
| 16. | Saliva ejector | 134.001 | Protection of the Patient during medical examination | 1 |
| 17. | Tissue Paper Alfa Soft 5kg | 106.503.A/S | Protection of the Patient during medical examination | 1 |
| 18. | Tissue Paper Alfa Soft 5kg-Folded | 106.603.A/S | Protection of the Patient during medical examination | 1 |
| 19. | Tissue Paper Alfa Soft 1kg | 106.103.A/S | Protection of the Patient during medical examination | 1 |
| 20. | Tissue Paper Alfa Soft 300gr | 106.303.A/S | Protection of the Patient during medical examination | 1 |
| 21. | Tissue Paper Extra Soft 5kg | 106.502.E/S | Protection of the Patient during medical examination | 1 |
| 22. | Tissue Paper Extra Soft 5kg-Folded | 106.602.E/S | Protection of the Patient during medical examination | 1 |
| 23. | Tissue Paper Extra Soft 1kg | 106.102.E/S | Protection of the Patient during medical examination | 1 |
| 24. | Tissue Paper Extra Soft 300gr | 106.302.E/S | Protection of the Patient during medical examination | 1 |
| 25. | Tissue Paper Extra Extra Soft 5kg | 106.504.E/S | Protection of the Patient during medical examination | 1 |
| 26. | Tissue Paper Extra Extra Soft 5kg-Folded | 106.604.E/E | Protection of the Patient during medical examination | 1 |
| 27. | Tissue Paper Extra Extra Soft 1kg | 106.104.E/E | Protection of the Patient during medical examination | 1 |
| 28. | Tissue Paper Extra Extra Soft 300gr | 106.304.E/E | Protection of the Patient during medical examination | 1 |
| 29. | Tissue Paper Alfa Alfa Soft 5kg | 106.501.A/A | Protection of the Patient during medical examination | 1 |
| 30. | Tissue Paper Alfa Alfa Soft 5kg-Folded | 106.601.A/A | Protection of the Patient during medical examination | 1 |
| 31. | Tissue Paper Alfa Alfa Soft 1kg | 106.101.A/A | Protection of the Patient during medical examination | 1 |
| 32. | Tissue Paper Alfa Alfa Soft 300gr | 106.301.A/A | Protection of the Patient during medical examination | 1 |

APPLIED STANDARDS & LEGAL REQUIREMENTS

ISO 13485:2016



| APPROVAL | |
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| NAME: | Prili Antigony |
| POSITION: | Quality Assurance Director |
| PLACE: | Kifisia |
| DATE: | 9/4/21 |
| SIGN: | <p>GEORGE BOURNAS & STAVROULA BOURNA C.O. "BOURNAS MEDICALS" MEDICAL & HOSPITAL PRODUCTS XRISTIDOU 13122 BRANCH 18, 11561 KIFISIA TEL: +302102622369 FAX: +302102612089 VAT NUMBER: EL 099067902 LOCAL REVENUE (TAXATION) OFFICE: AG. ANARGIRON</p> |