

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 2017/745 and where appropriate, the standards and legislation referred to.

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LIST OF PRODUCTS COVERED BY THIS DECLARATION

No	PRODUCT	CODE	BASIC UDI-DI	UDI-DI	INTENDED USE	RULE
1.	Elite thermal laminated examination roll	108.02x.ST	5208107106108109Z2	5208107001646	Protection of the Patient during medical examination	1
2.	Premium Laminated with glue examination roll	108.02x.SA	5208107106108109Z2	5208107001608	Protection of the Patient during medical examination	1
3.	Eco Laminated with glue examination roll	108.02x.SE	5208107106108109Z2	5208107001622	Protection of the Patient during medical examination	1
4.	Classic paper 2ply	108.01x.Sx	5208107106108109Z2	5208107001561	Protection of the	1

	examination roll				Patient during medical examination	
5.	Regular paper embossed 2ply examination roll	108.01x.SG	5208107106108109Z2	5208107001585	Protection of the Patient during medical examination	1
6.	Supreme Non-woven examination roll	108.03x.xx	5208107106108109Z2	5208107001660	Protection of the Patient during medical examination	1
7.	Prestige Non-woven + PE examination roll	108.04x.x	5208107106108109Z2	5208107001684	Protection of the Patient during medical examination	1
8.	Rainbow dental bib in sheets 2ply paper +1ply PE	108.081	5208107106108109Z2	5208107001721	Protection of the Patient during medical examination	1
9.	Rainbow dental bib in sheets 1ply paper +1ply PE	108.082	5208107106108109Z2	5208107001738	Protection of the Patient during medical examination	1
10.	Dental bibs on roll 30cm X 50m	108.061	5208107106108109Z2	5208107001707	Protection of the Patient during medical examination	1
11.	Rainbow head rest cover	109.201.x	5208107106108109Z2	5208107001745	Protection of the Patient during medical examination	1
12.	Dental bibs on roll with neckline	109.101.x	5208107106108109Z2	5208107001752	Protection of the Patient during medical examination	1
13.	Rainbow tray Paper	109.301.x	5208107106108109Z2	5208107001172	Protection of the Patient during medical examination	1
14.	Hyper air laid wipes	108.10x	5208107106108109Z2	5208107001790	Protection of the Patient during medical examination	1
15.	Hyper air laid wipes in roll	108.11x	5208107106108109Z2	5208107001813	Protection of the Patient during medical examination	1
16.	Saliva ejector	134.001	5208107106108109Z2	5208107001776	Protection of the Patient during medical examination	1
17.	Tissue Paper Alfa Soft 5kg	106.503.A/S	5208107106108109Z2	5208107001530	Protection of the Patient during medical examination	1
18.	Tissue Paper Alfa Soft	106.603.A/S	5208107106108109Z2	5208107001554	Protection of the	1

	5kg-Folded				Patient during medical examination	
19.	Tissue Paper Alfa Soft 1kg	106.103.A/S	5208107106108109Z2	5208107001523	Protection of the Patient during medical examination	1
20.	Tissue Paper Alfa Soft 300gr	106.303.A/S	5208107106108109Z2	5208107001509	Protection of the Patient during medical examination	1
21.	Tissue Paper Extra Soft 5kg	106.502.E/S	5208107106108109Z2	5208107001486	Protection of the Patient during medical examination	1
22.	Tissue Paper Extra Soft 5kg-Folded	106.602.E/S	5208107106108109Z2	5208107001493	Protection of the Patient during medical examination	1
23.	Tissue Paper Extra Soft 1kg	106.102.E/S	5208107106108109Z2	5208107001462	Protection of the Patient during medical examination	1
24.	Tissue Paper Extra Soft 300gr	106.302.E/S	5208107106108109Z2	5208107001448	Protection of the Patient during medical examination	1
25.	Tissue Paper Extra Extra Soft 5kg	106.504.E/S	5208107106108109Z2	5208107001424	Protection of the Patient during medical examination	1
26.	Tissue Paper Extra Extra Soft 5kg-Folded	106.604.E/E	5208107106108109Z2	5208107001431	Protection of the Patient during medical examination	1
27.	Tissue Paper Extra Extra Soft 1kg	106.104.E/E	5208107106108109Z2	5208107001387	Protection of the Patient during medical examination	1
28.	Tissue Paper Extra Extra Soft 300gr	106.304.E/E	5208107106108109Z2	5208107001400	Protection of the Patient during medical examination	1
29.	Tissue Paper Alfa Alfa Soft 5kg	106.501.A/A	5208107106108109Z2	5208107001363	Protection of the Patient during medical examination	1
30.	Tissue Paper Alfa Alfa Soft 5kg-Folded	106.601.A/A	5208107106108109Z2	5208107001370	Protection of the Patient during medical examination	1
31.	Tissue Paper Alfa Alfa Soft 1kg	106.101.A/A	5208107106108109Z2	5208107001325	Protection of the Patient during medical examination	1
32.	Tissue Paper Alfa Alfa	106.301.A/A	5208107106108109Z2	5208107001349	Protection of the	1

	Soft 300gr				Patient during medical examination	
33.	Bed Sheets	108.091	5208107106108109Z2	5208107001783	Protection of the Patient during medical examination	1

APPLIED STANDARDS & LEGAL REQUIREMENTS

ISO 13485:2016

APPROVAL

CE

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