




Declaration of conformity

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|  | The undersigned Domenico Lo Russo | |
| | as a legal representative of ELDO S.r.l. | |
| | based in: via Serro D'Annunzio 18 – 83050 – Vallesaccarda (AV) | |
| | VAT ID: IT03128600644 | |
| <i>Declares</i> | | |
| that the device: Dental retractors system | | |
| Model and code: Lo Russo Retractors – 141000; 141001; 141002; 141003; 141004; 141005; 141006 | | |
| Class: I | | Basic UDI-DI: 805894512141LR29 |
| Dmanufacturing date: see label | | Lot number: see label |
| was built in compliance with the following directives and standards: | | |
| <ul style="list-style-type: none">• Regulation (EU) 2017/745 Regulation on medical devices.• UNI CEI EN ISO 15223-1:2021 Title: Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements.• UNI CEI EN ISO 20417:2021 Medical devices - Information provided by the manufacturer.• UNI CEI EN 14971:2020 Application of risk management to medical devices.• Norma IEC 61882:2016 Risk analysis method according to the HAZOP method.• Directive 2001/95/CE "General Product Safety".• UNI EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity test.• EN ISO 17664-1:2017 Treatment of health products - Information to be provided by the manufacturer of the medical device for the treatment of medical devices - Part 1: Critical and semi-critical medical devices. | | |
| And complies with the said directives and regulations. | | |
| This declaration of conformity is issued under the responsibility of the manufacturer. | | |
| Place: Vallesaccarda | | Signature: <i>D.Lo Russo</i> |
| Date: 03-01-2023 | | Rev. 1 |