MAGNUM
DENTAL

Declaration of Conformity

Manufacturer	**Magnum Dental OÜ** Aardla 13 50112 Tartu Estonia
Company registration code	10351798
Single registration number	EE-MF-000037863
Notified body	DNV Product Assurance AS Veritasveien 1 1363 Høvik Norway
Notified body ID number	2460
Certification number	C-01-1125-669-19
Certificate coverage	Dental irrigation and cleansing solution
Classification	IIa according to Rule 6 transient use

Product name	Product code	Bottle size
Canasol 1%	226515	250 ml
Canasol 1%	226516	400 ml
R&S Hypoclorit 2,5%	3025793	500 ml
Kent Hypoclorit 2,5%	3025792	500 ml
Access Sodium Hypochlorite 2,5%	3153062	400 ml
Canasol 3%	226514	250 ml
Canasol 3%	226472	400 ml
CanalPro NaOCl 3%	65002866	500 ml
Calasept NaOCl 3%	1290300	400 ml
Parcan L	245595	400 ml
Henry Schein NaOCl 3%	572-3791	500 ml
DE Healthcare Products NaOCl 3%	97-99527	500 ml
IrriGance 3%	21420	400 ml
IrriGance 6%	21421	400 ml
Access Sodium Hypochlorite 5,25%	3162100	400 ml
Canasol 6%	226639	250 ml
Canasol 6%	228673	400 ml
CanalPro NaOCl 6%	65002867	500 ml
Calasept NaOCl 6%	1290600	400 ml
CHX Endo 0,2%	228674	400 ml
CHX Endo 2%	226627	250 ml
CHX Endo 2%	228670	400 ml
CanalPro CHX 2%	60019659	100 ml
CanalPro CHX 2%	60019658	500 ml
Calasept CHX 2%	1270100	250 ml
R4 Ultra	248865	250 ml
EDTA 17%	216243	250 ml
EDTA 17%	228667	400 ml

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CanalPro EDTA 17%	60019654	100 ml
CanalPro EDTA 17%	60019651	500 ml
Calasept EDTA 17%	1260100	250 ml
Largal L	248866	250 ml

We confirm that the products are manufactured according to the product specifications and the shelf-life of the products is 24 months from the manufacturing date.

We, with sole responsibility in drawing up this declaration of conformity, declare that the above mentioned product meets the provisions and is manufactured (inc. designing, producing, packaging) according to EC Council Directives, Harmonized standards (as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council), Estonian national law and technical documentation.

All supporting documentation is retained under the premises of the manufacturer.

DIRECTIVES and Acts

General applicable directives and Acts:

COUNCIL DIRECTIVE 93/42/EEC amended by directive 2007/47/EC concerning medical devices.
Annex V Section 3 of Medical Device Directive 93/42/EEC
Medical device act 13.10.2004 (Estonian) and related regulations

This Declaration is issued under the transitional provisions of Article 120(3) of Regulation (EU) 2017/745. The manufacturer declares compliance with the conditions laid down therein.

This Declaration of Conformity updates the previous DoC drawn up on 10.05.2023 to cover all brand names in one document.

Laagri, Estonia 28.01.2026

Sirli Puhk
Member of the Management Board

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