EU Declaration of Conformity

This declaration is issued under the sole responsibility of Heka Dental A/S.
Heka Dental A/S, the manufacturer of below-mentioned product, hereby declare that it complies with the relevant provisions of the Medical Device Regulation 2017/745/EU of the European Parliament and the Counsel in accordance with Annex I, General Safety and Performance Requirements and Annex IX, Conformity Assessment based on a Quality Management System and on an Assessment of Technical Documentation as verified by the DNV Product Assurance AS CE:2460. This declaration is supported by the Quality System approval of ISO 13485:2016 certified by DNV Product Assurance AS CE:2460
This declaration and all belonging documentation are retained at the location of the manufacture.

Product information	Manufacture & Address	Heka Dental A/S, Litauen Alle 4, DK-2630 Taastrup, Denmark. Phone/Fax: +45 43320990/+4543320980 Mail/Web: mail@heka-dental.dk/www.heka-dental.dk
	Brand name/ family/ number:	Heka Product: Heka UnicLine S Number:M-540 Heka Product: Heka UnicLine S Pillar Number:M-543 --- Heka Product: Heka S + Number:M-541 Heka Product: Heka S + Pillar Number:M-542 Heka Product: Heka G + Number:M-546
	Intended purpose:	Heka Dental Family Systems are dental units. The system is intended for use in dental care treatments. The system is to be used by authorized professionals within the scope of his/her education, training, and experience. The system provides the dental practitioner a motorized patient chair, dental instruments, and suction system for removal of bodily fluids.
	SRN-number:	DK-MF-000003848

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	Basic UDI-DI:	UnicLine S = 5745000017027 *Variant*: Heka I pillar = 5745000017096 Heka S+ = 5745000017034 *Variant*: Heka I+ pillar = 5745000017102 Heka G+ = 5745000017058
	Device Classification:	Dental treatment Center is an active device which is intended to administer energy to other dental devices (rule 9) Class IIa. Rule 9 indent 1 All active therapeutic devices intended to administer or exchange energy are classified as class IIa
	CND code:	Q01
	Common specifications:	N/A
	Quality System Certificate:	C525825 NA DNK, Valid until: 2026-06-02
	EC Certificate:	10000372586-PA-NA-DNK Rev 0.0
	CE Marking date MDD:	17.12.2015 UnicLine S 23.11.2020 Heka S+ & Heka G+ Variants approved 23.07.2025
Notified Body:		DNV Product Assurance AS, CE 2460, Veritasveien 3, 1363 Høvik, Norway Tel +47 67 57 88 00, www.dnv.com

Denmark, Taastrup, 2025-07-25

Claus van der Goot

Quality & regulatory Affairs (PRRC)

Asbjørn Nielsen

Managing Director

Signed