

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 Council 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
		Heka Chair: Heka Patient Chair	Number: SB-0900
	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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HEKA
DENTAL®

	Basic UDI-DI:	UnicLine S	5745000017027
		Variant: Heka I pillar	5745000017096
		Heka S+	5745000017034
		Variant: Heka I+ pillar	5745000017102
		Heka G+	5745000017058
		Heka Patient Chair	5745000017126
	Device Classification:	A Heka dental unit 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. Heka patient chairs are intended to support a patient during a dental treatment and are classified as Class I devices.	
	CND (EMDN) code:	Q01	
	Common specifications:	N/A	
	Quality System Certificate:	C525825 NA DNK, Valid until: 2029-06-02	
	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, 2026-06-02



Claus van der Goot

Quality & regulatory Affairs (PRRC)



Asbjørn Nielsen

Managing Director