Declaration of Conformity

This Declaration of Conformity covers the European Medical Device Regulation 2017/745. The information included in this declaration fulfills the requirements in Annex IV, EU Declaration of Conformity. The devices covered by the present declaration is in conformity with the listed regulations.

Manufacturer	
Name, registered trade name or registered trademark	CMS Dental A/S
Single registration number, SRN	Manufactures SRN identification shall be issued by Danish Health and Medicines Authority before May 26th 2022.
Danish Health and Medicines Authority, NCA code	DK-CA-001
Eudamed reference	DK-CA-001
Address	Elmevej 8, 7870 Roslev, Denmark

Product Information	
Product description	Size Verifier
Intended purpose	The Size Verifier is intended to secure that there is enough space in the prepared root canal for the obturator to fit in. The Size Verifier is an accessory to the obturator product. It is a helpful tool for the Dentist but not a necessary tool to complete the root canal filling satisfactorily. It is NOT a measuring device.
Risk class	Class I
References to CS used	There are no Common Specification available for this type of products in the Official Journal of the European Union.

Notified Body	
Name	DNV GL Presafe AS
Notified Body identification number	2460
Conformity assessment procedure	Quality Management System – Medical devices ISO 13485:2016/NS-EN ISO 13485: 2016 Medical Device Regulation 2017/745 Annex II (TD) Annex III (PMS) Annex IX, Chapter I (QMS) (Annex IX, Chapter III) [only a requirement outside of EU] Article 19/Annex IV (DoC)
Identification of certificate(s)	Quality Management System – Medical devices ISO 13485:2016 / EN ISO 13485:2016 Certificate number: 268826-2018-AQ-NOR-NA-PS Rev.1.0 Issue date: 30 September 2021 Valid until: 10 December 2024 Issued by: DNV Product Assurance AS

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Regulation 2017/745 and its relevant transposition into national laws of the member states into which we place the device. The manufacturer is exclusively responsible for the declaration of conformity.

Declaration of Conformity

Approval	
On behalf of CMS Dental A/S Signature	
Name / Function	Lisbeth Rose / Quality Director
Place	Copenhagen
Date of issue	2021-12-10

Appendix – List of products

Products

Product and trade name	Item no.	UDI	Eudamed reference
Soft-Core Size Verifier			
Soft-Core Size Verifier, #20, 6 pcs	*SSV6/20*	571322300055	To be defined
Soft-Core Size Verifier, #25, 6 pcs	*SSV6/25*	571322300056	To be defined
Soft-Core Size Verifier, #30, 6 pcs	*SSV6/30*	571322300057	To be defined
Soft-Core Size Verifier, #35, 6 pcs	SSV6/35	571322300058	To be defined
Soft-Core Size Verifier, #40, 6 pcs	SSV6/40	571322300059	To be defined
Soft-Core Size Verifier, #45, 6 pcs	SSV6/45	571322300060	To be defined
Soft-Core Size Verifier, #50, 6 pcs	SSV6/50	571322300061	To be defined
Soft-Core Size Verifier, #55, 6 pcs	SSV6/55	571322300062	To be defined
Soft-Core Size Verifier, #60, 6 pcs	SSV6/60	571322300063	To be defined
One-Step Size Verifier			
One-Step Size Verifier, #20, 6 pcs	OSV6/20	571322300101	To be defined
One-Step Size Verifier, #25, 6 pcs	OSV6/25	571322300102	To be defined
One-Step Size Verifier, #30, 6 pcs	OSV6/30	571322300103	To be defined
One-Step Size Verifier, #35, 6 pcs	OSV6/35	571322300104	To be defined
One-Step Size Verifier, #40, 6 pcs	OSV6/40	571322300105	To be defined
One-Step Size Verifier, #50, 6 pcs	OSV6/50	571322300106	To be defined
One-Step Size Verifier, #60, 6 pcs	OSV6/60	571322300107	To be defined

Document history

Version	Created Date / Name	Description/Addition/Change
v1	22-11-2021 / MS	Creation of document as part of MDD to MDR transfer.