

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 that are covered by the present declaration is in conformity with the above regulation.

Manufacturer	
Name, registered trade name or registered trademark	CMS Dental A/S
Single registration number, SRN	Currently not available from Danish Health and Medicines Authority
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 Verifiers for Endodontic Obturators
Product and trade names	See appendix list of products
Intended purpose	The intended purpose of the size verifier is to determine that the root canal has been cleaned out sufficiently in all dimensions before choosing the right size obturator and performing obturation. After the mechanical preparation of the root canal, the size verifier is inserted to apex and if it goes all the way to apex, it shows that there is enough three-dimensional space for the matching obturator size. Size Verifier #25 is corresponding Obturator #25 etc.
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	<u>Quality Management System – Medical devices</u> ISO 13485:2016/NS-EN ISO 13485: 2016 <u>Medical Device Regulation 2017/745</u> 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)	<u>Quality Management System – Medical devices</u> ISO 13485:2016/NS-EN ISO 13485: 2016 Certificate number: 268826-2018-AQ-NOR-NA-PS Rev. 0.0 Issue date: 11 December 2018 Valid until: 10 December 2021 Issued by: DNV GL Presafe 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.

Approval	
On behalf of CMS Dental A/S	
Signature	
Name / Function	Lisbeth Rose / Quality Manager
Place	Copenhagen
Date of issue	2021-03-12

See appendix list of products on following pages

DoC Appendix - List of products

Brand: CMS Dental

Product and trade name	Item no.	UDI	Eudamed reference
<u>Soft-Core Size Verifier</u>			
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
<u>One-Step Size Verifier</u>			
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

DoC Appendix - List of products

Brand: Micro Mega

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
HEROfill Verifier, #20, 6 pcs	20139501N	20139501N	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
HEROfill Verifier, #25, 6 pcs	20139502N	20139502N		
HEROfill Verifier, #30, 6 pcs	20139503N	20139503N		
HEROfill Verifier, #35, 6 pcs	20139504N	20139504N		
HEROfill Verifier, #40, 6 pcs	20139505N	20139505N		
HEROfill Verifier, #45, 6 pcs	20139506N	20139506N		
HEROfill Verifier, Ass, 6 pcs	20139514N	20139514N		

DoC Appendix - List of products

Brand: Pearson Dental

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
Vivid EndoCore Size Verifier, #20, 6 pcs	C36-0154	C36-0154	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
Vivid EndoCore Size Verifier, #25, 6 pcs	C36-0156	C36-0156		
Vivid EndoCore Size Verifier, #30, 6 pcs	C36-0158	C36-0158		
Vivid EndoCore Size Verifier, #35, 6 pcs	C36-0160	C36-0160		
Vivid EndoCore Size Verifier, #40, 6 pcs	C36-0162	C36-0162		
Vivid EndoCore Size Verifier, #45-60, 6 pcs	C36-0164	C36-0164		

DoC Appendix - List of products

Brand: Gebr. Brasseler

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
F360 Fill Verifier, #20, 6 pcs	044454K1	044454K1	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
F360 Fill Verifier, #25, 6 pcs	044455K1	044455K1		
F360 Fill Verifier, #30, 6 pcs	044456K1	044456K1		
F360 Fill Verifier, #35, 6 pcs	044457K1	044457K1		
F360 Fill Verifier, #40, 6 pcs	044458K1	044458K1		
F360 Fill Verifier, #45, 6 pcs	044459K1	044459K1		

DoC Appendix - List of products

Brand: Dentalica

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
Precision Thermo GP Size Verifier, #20, 6 pcs	PR0025V20	PR0025V20	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
Precision Thermo GP Size Verifier, #20-30, 6 pcs	PR0025V20-30	PR0025V20-30		
Precision Thermo GP Size Verifier, #25, 6 pcs	PR0025V25	PR0025V25		
Precision Thermo GP Size Verifier, #30, 6 pcs	PR0025V30	PR0025V30		
Precision Thermo GP Size Verifier, #35, 6 pcs	PR0025V35	PR0025V35		
Precision Thermo GP Size Verifier, #40, 6 pcs	PR0025V40	PR0025V40		
Precision Thermo GP Size Verifier, #50, 6 pcs	PR0025V50	PR0025V50		
Precision Thermo GP Size Verifier, #55, 6 pcs	PR0025V55	PR0025V55		
Precision Thermo GP Size Verifier, #60, 6 pcs	PR0025V60	PR0025V60		

DoC Appendix - List of products

Brand: Kerr

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
<u>Soft-Core Classic</u>				
Soft-Core Size Verifier, #20, 6pcs	065-0246	972-3220	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
Soft-Core Size Verifier, #25, 6pcs	065-0247	972-3225		
Soft-Core Size Verifier, #30, 6pcs	065-0248	972-3230		
Soft-Core Size Verifier, #35, 6pcs	065-0249	972-3235		
Soft-Core Size Verifier, #40, 6pcs	065-0250	972-3240		
Soft-Core Size Verifier, #45, 6pcs	065-0251	972-3245		
Soft-Core Size Verifier, #50, 6pcs	065-0252	972-3250		
Soft-Core Size Verifier, #55, 6pcs	065-0253	972-3255		
Soft-Core Size Verifier, #60, 6pcs	065-0254	972-3260		
<u>K3/K3XF</u>				
K3/K3XF Size Verifier, #20, 6pcs	065-0493	065-0493	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
K3/K3XF Size Verifier, #25, 6pcs	065-0494	065-0494		
K3/K3XF Size Verifier, #30, 6pcs	065-0495	065-0495		
K3/K3XF Size Verifier, #35, 6pcs	065-0496	065-0496		
K3/K3XF Size Verifier, #40, 6pcs	065-0497	065-0497		
K3/K3XF Size Verifier, #45, 6pcs	065-0498	065-0498		
K3/K3XF Size Verifier, #50, 6pcs	065-0499	065-0499		
K3/K3XF Size Verifier, #55, 6pcs	065-0502	065-0502		
K3/K3XF Size Verifier, #60, 6pcs	065-0503	065-0503		
<u>TF Adaptive</u>				
TF Adaptive Size Verifier, SM2, 6 pcs	065-0487	815-1552	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
TF Adaptive Size Verifier, SM3, 6 pcs	065-0488	815-1553		
TF Adaptive Size Verifier, ML1, 6 pcs	065-0489	815-1557		
TF Adaptive Size Verifier, ML2, 6 pcs	065-0491	815-1558		
TF Adaptive Size Verifier, ML3, 6 pcs	065-0492	815-1559		

DoC Appendix - List of products

Brand: Nueva Galimplant

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
Verificador Endogal, #20, 6 pcs	VT020	VT020	To be defined before 26 Maj 2025 (MDR Article 27)	To be defined
Verificador Endogal, #25, 6 pcs	VT025	VT025		
Verificador Endogal, #30, 6 pcs	VT030	VT030		
Verificador Endogal, #35, 6 pcs	VT035	VT035		
Verificador Endogal, #40, 6 pcs	VT040	VT040		
Verificador Endogal, #45, 6 pcs	VT045	VT045		
Verificador Endogal, #50, 6 pcs	VT050	VT050		