



### Annex IV EU Declaration of Conformity

<b>Manufacturer Name and Address:</b>	Kerr Italia, S.r.l. Via Passanti, 174 Scafati (SA), 84018, Italy
<b>Authorized Representative Name and Address:</b>	N/A
<b>Single Registration Number (SRN):</b>	IT-MF-000007768
<b>Technical File Name/Number:</b>	Matrix and Interdental Wedge / R108
<b>Basic UDI-DI:</b>	See Attachment 1
<b>Product Tradename(s):</b>	See Attachment 1
<b>Device Identification:</b>	See Attachment 1
<b>Classification and Rule(s):</b>	Class I, Rule 5 (Annex VIII)
<b>Intended Purpose:</b>	Matrix is intended to rebuild the healthy anatomical shape of the human tooth to restore a physiological chewing process and Interdental Wedges are intended to separate the teeth to help in slipping the matrix band between the unprepared teeth.
<b>Notified Body:</b>	Not Applicable
<b>Notified Body Number:</b>	Not Applicable
<b>Conformity Assessment Procedure &amp; Certificate issued:</b>	Annex IV, Certificate Not Applicable
<b>Common Standards:</b>	See Attachment 2

#### Declaration Statement:

*This declaration of conformity is issued under the sole responsibility of Kerr Italia S.r.l. We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.*

**Signed for and on behalf of Manufacturer: Kerr Italia S.r.l.**

Brea, California, USA  
Place

18-Aug-2023 | 04:03 CEST

Date of Issue

DocuSigned by:

*Jennifer Evans*  
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Name: Jennifer Evans  
Title: Vice President, Regulatory Affairs  
and Quality Assurance



<b>Matrix and Interdental Wedges - Technical File R108</b>		
<b>Attachment 1 to Annex IV EC Declaration of Conformity</b>		
<b>REF</b>	<b>Description</b>	<b>Basic UDI-DI</b>
822/05	Hawe Interdental Wedges – Mini Turquoise	80515118710000475J
822/10	Hawe Interdental Wedges – Orange	80515118710000475J
822/20	Hawe Interdental Wedges - White	80515118710000475J
822/30	Hawe Interdental Wedges - Green	80515118710000475J
822/40	Hawe Interdental Wedges - Yellow	80515118710000475J
822/50	Hawe Interdental Wedges - Blue	80515118710000475J
822/60	Hawe Interdental Wedges - Red	80515118710000475J
822/70	Hawe Interdental Wedges - White	80515118710000475J
829/05	Hawe Interdental Wedges – Mini Turquoise	80515118710000475J
829/10	Hawe Interdental Wedges - Orange	80515118710000475J
829/20	Hawe Interdental Wedges - White	80515118710000475J
829/30	Hawe Interdental Wedges - Green	80515118710000475J
829/40	Hawe Interdental Wedges - Yellow	80515118710000475J
829/50	Hawe Interdental Wedges - Blue	80515118710000475J
829/60	Hawe Interdental Wedges - Red	80515118710000475J
829/70	Hawe Interdental Wedges - White	80515118710000475J
823	Hawe Interdental Wedges Colour Coded, Ass.	80515118710000475J
826	Hawe Interdental Wedge - Assortment	80515118710000475J
827	Hawe Interdental Wedges - Assortment	80515118710000475J
405	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
406	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
407	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
408	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
409	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
410	Hawe Matrices Micro-Thin 0,03 MM	80515118710000485L
2161	Adapt Supercap Matrix Stahl 5 mm	80515118710000485L
2162	Adapt Supercap Matrix Stahl 6,3	80515118710000485L
2171	Adapt Supercap Matrix Tran. 5mm	80515118710000485L
2172	Adapt Supercap Matrix Tran. 6,3	80515118710000485L
2181	Adapt Supercap Matrix Tof. 5mm	80515118710000485L
2182	Adapt Supercap Matrix Tof. 6,3	80515118710000485L
2775	Blue Lucifix Premolar Matrices	80515118710000485L
2776	Blue Lucifix Molar Matrices (50 EA)	80515118710000485L
3601	METAFIX Refill Small	80515118710000485L
3602	METAFIX Refill Medium	80515118710000485L
3603	METAFIX Refill Large	80515118710000485L
3604	METAFIX Kit	80515118710000485L
756	Hawe Transparent Adapt Sectional Matrices 5 Mm	805151187100005057
757	Hawe Transparent Adapt Sectional Matrices 6,5 Mm	805151187100005057
758	Hawe Transparent Adapt Sectional Matrices 5 Mm	805151187100005057



<b>Attachment 1 (Continued)</b>		
<b>REF</b>	<b>Description</b>	<b>Basic UDI-DI</b>
759	Hawe Transparent Adapt Sectional Matrices 6,5 Mm	805151187100005057
861	Holder For Transparent Cervical Matrices	805151187100005159
2160	SUPERMAT, confezionato in tubo	80515118710000525B
640	Hawe Stopstrip Assortment Straight	80515118710000535D
641	Hawe Stopstrip Straight, 8 MM	80515118710000535D
642	Hawe Stopstrip Straight, 10 MM	80515118710000535D
650	Hawe Stopstrip Assortment Curved	80515118710000535D
651	Hawe Stopstrip Curved, 8 MM	80515118710000535D
652	Hawe Stopstrip Curved, 10 MM	80515118710000535D
690	Hawe Transparent Strips Straight, 6 MM	80515118710000535D
691	Hawe Transparent Strips Straight, 8 MM	80515118710000535D
692	Hawe Transparent Strips Straight, 10 MM	80515118710000535D
695	Hawe Transparent Strips Curved, 6 MM	80515118710000535D
696	Hawe Transparent Strips Curved, 8 MM	80515118710000535D
697	Hawe Transparent Strips Curved, 10 MM	80515118710000535D
750	Hawe Transparent Adapt Sectional Matrix Ass.	80515118710000545F
755	Hawe Adapt Sectional Matrices Application Forceps	80515118710000555H
2150	SUPERMAT Assort.	80515118710000565K
850 S	Transparent Cervical Matrices Soft Ass.	80515118710000575M
851 S	Hawe Transparent Cervical Matrices soft	80515118710000575M
852 S	Hawe Transparent Cervical Matrices	80515118710000575M
853 S	Hawe Transparent cervical matrices soft	80515118710000575M
854 S	Hawe Transparent Cervical matrices soft	80515118710000575M
855 S	Hawe Transparent Cervical matrices soft	80515118710000575M
856 S	Hawe Transparent Cervical Foils Soft Universal	80515118710000575M
857 S	Hawe Transparent Cervical Foils Soft Universal Molar	80515118710000575M
730	Adapt Luciwedge Ass.	80515118710000585P
731	Adapt Luciwedge Small	80515118710000585P
732	Adapt Luciwedge Medium	80515118710000585P
733	Adapt Luciwedge Large	80515118710000585P
734	Adapt Luciwedge Ultra Small	80515118710000585P
770 S	Luciwedge Soft, Ultra Slim	80515118710000585P
771 S	Luciwedge Soft, Small	80515118710000585P
772 S	Luciwedge Soft, Medium	80515118710000585P
790 S	Luciwedge, Ass. Soft	80515118710000585P
773	Hawe Transparent Premolar Bands	80515118710000595R
774	Hawe Transparent Molar Bands	80515118710000595R
775	Lucifix Transparent Premolar Matrix Bands	80515118710000595R
776	Lucifix Transparent Molar Matrix Bands	80515118710000595R
830	Hawe Wedge System Kit	80515118710000475J
820	Wedge Positioner	80515118710000605A



<b>Attachment 1 (Continued)</b>		
<b>REF</b>	<b>Description</b>	<b>Basic UDI-DI</b>
399 A	Hawe STEEL BAND EE, 5 MM	80515118710000625E
399 B	Hawe STEEL BAND EE, 6 MM	80515118710000625E
399 C	Hawe STEEL BAND EE, 7 MM	80515118710000625E
499 A	Hawe STEEL BAND 0,045 MM, 5 MM	80515118710000625E
499 B	Hawe STEEL BAND 0,045 MM, 6 MM	80515118710000625E
499 C	Hawe STEEL BAND 0,045 MM, 7 MM	80515118710000625E
2685	Hawe BLUE STRIPROLL 6MM	80515118710000635G
2686	Hawe BLUE STRIPROLL 8MM	80515118710000635G
2687	Hawe BLUE STRIPROLL 10MM	80515118710000635G
680	Hawe ADAPT TRANSPARENT STRIPS	80515118710000645J
685	Hawe TRANSPARENT STRIPROLL, 6 MM/15 M	80515118710000655L
686	Hawe TRANSPARENT STRIPROLL, 8 MM/15 M	80515118710000655L
687	Hawe TRANSPARENT STRIPROLL, 10 MM/15 M	80515118710000655L
2010	SUPERCAP-SOLO BOBINA 5,6MM 100PCS	80515118710000665N
2015	SUPERCAP-SOLO BOBINA 6,7MM 100PCS	80515118710000665N
2020	SUPERCAP-SOLO BOBINA 5,6MM 500PCS	80515118710000665N
2025	SUPERCAP-SOLO BOBINA 6,7MM 500PCS	80515118710000665N
375	Hawe Adapt Matrices	805151187100008962
376	Hawe Adapt Matrices	805151187100008962
377	Hawe Adapt Matrices	805151187100008962
378	Hawe Adapt Matrices	805151187100008962
379	Hawe Adapt Matrices	805151187100008962
380	Hawe Adapt Matrices	805151187100008962
382	Hawe Adapt Matrices	805151187100008962
390	Hawe Precontoured Matrices	80515118710000905K
391	Hawe Precontoured Matrices	80515118710000905K
392	Hawe Precontoured Matrices	80515118710000905K
393	Hawe Precontoured Matrices	80515118710000905K
394	Hawe Precontoured Matrices	80515118710000905K
395	Hawe Precontoured Matrices	80515118710000905K
1201	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1202	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1203	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1204	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1205	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1206	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1207	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M
1208	Hawe Matrices Super-Thin 0,038 MM	80515118710000915M



<b>Attachment 1 (Continued)</b>		
<b>REF</b>	<b>Description</b>	<b>Basic UDI-DI</b>
1501	Hawe Titanium Matrices	80515118710000925P
1502	Hawe Titanium Matrices	80515118710000925P
1506	Hawe Titanium Matrices	80515118710000925P
1507	Hawe Titanium Matrices	80515118710000925P
1590	Hawe Contoured Titanium Matrices (30 EA)	80515118710000935R
1591	Hawe Contoured Titanium Matrices (30 EA)	80515118710000935R
1001 C	Hawe Contoured Tofflemire Bands, 0.05 Mm	80515118710000935R
1001/30	Hawe Tofflemire Matrices	80515118710000945T
1002/30	Hawe Tofflemire Matrices	80515118710000945T
1003/30	Hawe Tofflemire Matrices	80515118710000945T
1013/30	Hawe Tofflemire Matrices	80515118710000945T
1015/30	Hawe Tofflemire Matrices	80515118710000945T
1101 C	Tofflemire Contoured Matrices	80515118710000955V
1101/30	Hawe Tofflemire Matrices 0.038	80515118710000965X
1102/30	Hawe Tofflemire Matrices 0.038	80515118710000965X
1103/30	Hawe Tofflemire Matrices 0.038	80515118710000965X
1113/30	Hawe Tofflemire Matrices 0.038	80515118710000965X
1115/30	Hawe Tofflemire Matrices 0.038	80515118710000965X
2750	Hawe Blue Adapt Sectional Matrix Kit	80515118710000975Z
2751	Hawe Blue Adapt Sectional Matrix Moderate Curve 5 x 0.05	805151187100009863
2752	Hawe Blue Adapt Sectional Matrix Moderate Curve 6.5 x 0.05	805151187100009863
2753	Hawe Blue Adapt Sectional Matrix Increased Curve 5 x 0.05	805151187100009863
2754	Hawe Blue Adapt Sectional Matrix Increased Curve 6.5 x 0.05	805151187100009863
751	Hawe Transparent Adapt Sectional Matrix, 5 mm	805151187100009965
752	Hawe Transparent Adapt Sectional Matrix, 6,5 mm	805151187100009965
753	Hawe Transparent Adapt Sectional Matrix, 5 mm	805151187100009965
754	Hawe Transparent Adapt Sectional Matrix, 6,5 mm	805151187100009965
780 S	Hawe Transparent Posterior Matrix System soft	80515118710001004V
785 S	Transparent Lucifix Matrix System	80515118710001014X



<b>Matrix and Interdental Wedges - Common Standards Attachment 2</b>	
<b>Standard</b>	<b>Title</b>
EN ISO 13485:2016 /AC:2018	Medical Devices - Quality management systems
EN ISO 20417:2021	Medical Devices - Information to be supplied by the manufacturer
EN 1639:2009	Dentistry – Medical devices for dentistry – instruments
ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols
ISO 7405:2018	Surgical instruments – Materials – Part 1: Metals Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
BS EN ISO 9687:2015+A1:2018	Dentistry — Graphical symbols for dental equipment
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2009	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 13485:2016	Medical Devices – Quality management systems
EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
ISO 15098:2021	Medical devices. Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ASTM F1980 – 16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ISTA 2A:2011	Partial Simulation Performance Test for Packaged-Products 150 lbs or Less
MEDDEV 2.7.1 Rev 4:	Clinical Evaluation: A guide for manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC.