

Annex IV EC Declaration of Conformity

Manufacturer Name and Address: KerrHawe SA
Via Strecce 4, 6934 Bioggio, Switzerland

Authorized Representative Name and Address: Kerr Italia S.r.l.
Via Passanti, 332, 84018 Scafati (SA) Italy

Single Registration Number (SRN): Not available

Technical File Name/Number: KBI-IDN19009-TF – Rev 8

Basic UDI-DI: See Attachment 1

Product Tradename(s): Matrix and Interdental Wedge

Device Identification: See Attachment 1

Classification and Rule(s): Class I, Rule 5

Common Standards: Not available

Notified Body: Not applicable

Notified Body Number: Not applicable

Conformity Assessment Procedure & Certificate issued: Annex IX of MDR 2017/745

Declaration Statement:

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

Regulatory Affairs Signature:

Place and Issue date:

Bioggio, 11 March 2021



Name: Galileo Bertolasi

Title: QA/RA Director – Kerr Europe

KBI-IDN19009-TF - Attachment 1 to Annex IV EC Declaration of Conformity		
REF	Description	Basic UDI-DI
822/05	Hawe Interdental Wedges – Mini Turquoise	7611048000001TG
822/10	Hawe Interdental Wedges – Orange	
822/20	Hawe Interdental Wedges - White	
822/30	Hawe Interdental Wedges - Green	
822/40	Hawe Interdental Wedges - Yellow	
822/50	Hawe Interdental Wedges - Blue	
822/60	Hawe Interdental Wedges - Red	
822/70	Hawe Interdental Wedges - White	
829/05	Hawe Interdental Wedges – Mini Turquoise	
829/10	Hawe Interdental Wedges - Orange	
829/20	Hawe Interdental Wedges - White	
829/30	Hawe Interdental Wedges - Green	
829/40	Hawe Interdental Wedges - Yellow	
829/50	Hawe Interdental Wedges - Blue	
829/60	Hawe Interdental Wedges - Red	
829/70	Hawe Interdental Wedges - White	
823	Hawe Interdental Wedges Colour Coded, Ass.	
826	Hawe Interdental Wedge - Assortment	
827	Hawe Interdental Wedges - Assortment	
405	Hawe Matrices Micro-Thin 0,03 MM	
406	Hawe Matrices Micro-Thin 0,03 MM	
407	Hawe Matrices Micro-Thin 0,03 MM	
408	Hawe Matrices Micro-Thin 0,03 MM	
409	Hawe Matrices Micro-Thin 0,03 MM	
410	Hawe Matrices Micro-Thin 0,03 MM	
2161	Adapt Supercap Matrix Stahl 5 mm	
2162	Adapt Supercap Matrix Stahl 6,3	
2171	Adapt Supercap Matrix Tran. 5mm	

2172	Adapt Supercap Matrix Tran. 6,3	
2181	Adapt Supercap Matrix Tof. 5mm	
2182	Adapt Supercap Matrix Tof. 6,3	
3601	METAFIX Refill Small	
3602	METAFIX Refill Medium	
3603	METAFIX Refill Large	
2775	Blue Lucifix Premolar Matrices	
2776	Blue Lucifix Molar Matrices (50 EA)	
719	Cervical Matrices Metal	7611048000003TL
720	Cervical Matrices Metal	
721	Cervical Matrices Metal	
722	Cervical Matrices Metal	
723	Cervical Matrices Metal	
756	Hawe Transparent Adapt Sectional Matrices 5 Mm	7611048000005TQ
757	Hawe Transparent Adapt Sectional Matrices 6,5 Mm	
758	Hawe Transparent Adapt Sectional Matrices 5 Mm	
759	Hawe Transparent Adapt Sectional Matrices 6,5 Mm	
861	Holder For Transparent Cervical Matrices	7611048000006TS
2160	SUPERMAT, confezionato in tubo	7611048000004TN
640	Hawe Stopstrip Assortment Straight	7611048000007TU
641	Hawe Stopstrip Straight, 8 MM	
642	Hawe Stopstrip Straight, 10 MM	
650	Hawe Stopstrip Assortment Curved	
651	Hawe Stopstrip Curved, 8 MM	
652	Hawe Stopstrip Curved, 10 MM	
690	Hawe Transparent Strips Straight, 6 MM	
691	Hawe Transparent Strips Straight, 8 MM	
692	Hawe Transparent Strips Straight, 10 MM	
695	Hawe Transparent Strips Curved, 6 MM	
696	Hawe Transparent Strips Curved, 8 MM	
697	Hawe Transparent Strips Curved, 10 MM	

750	Hawe Transparent Adapt Sectional Matrix Ass.	76110481000013G8
755	Hawe Adapt Sectional Matrices Application Forceps	76110481000014GA
2150	SuperMat Assort.	76110481000015GC
850 S	Transparent Cervical Matrices Soft Ass.	76110481000020G5
851 S	Hawe Transparent Cervical Matrices soft	
852 S	Hawe Transparent Cervical Matrices	
853 S	Hawe Transparent cervical matrices soft	
854 S	Hawe Transparent Cervical matrices soft	
855 S	Hawe Transparent Cervical matrices soft	
856 S	Hawe Transparent Cervical Foils Soft Universal	
857 S	Hawe Transparent Cervical Foils Soft Universal Molar	
730	Adapt Luciwedge Ass.	
731	Adapt Luciwedge Small	
732	Adapt Luciwedge Medium	
733	Adapt Luciwedge Large	
734	Adapt Luciwedge Ultra Small	
770 S	Luciwedge Soft, Ultra Slim	
771 S	Luciwedge Soft, Small	
772 S	Luciwedge Soft, Medium	
790 S	Luciwedge, Ass. Soft	
773	Hawe Transparent Premolar Bands	76110481000022G9
774	Hawe Transparent Molar Bands	
775	Lucifix Transparent Premolar Matrix Bands	
776	Lucifix Transparent Molar Matrix Bands	
820	Wedge Positioner	76110481000023GB
830	Hawe Wedge System Kit	76110481000024GD
399 A	Hawe Steel Band EE, 5 MM	76110481000027GK
399 B	Hawe Steel Band EE, 6 MM	
399 C	Hawe Steel Band EE, 7 MM	
499 A	Hawe Steel Band 0,045 MM, 5 MM	
499 B	Hawe Steel Band 0,045 MM, 6 MM	

499 C	Hawe Blue Striproll 0,045 MM, 7 MM	
2685	Hawe Blue Striproll 6MM	
2686	Hawe Blue Striproll 8MM	76110481000028GM
2687	Hawe Blue Striproll 10MM	
680	Hawe Adapt Transparent Strips	
685	Hawe Transparent Striproll, 6 MM/15 M	76110481000030G8
686	Hawe Transparent Striproll, 8 MM/15 M	
687	Hawe Transparent Striproll, 10 MM/15 M	
2010	Supercap-Solo Bobina 5,6MM 100PCS	76110481000031GA
2015	Supercap-Solo Bobina 6,7MM 100PCS	
2020	Supercap-Solo Bobina 5,6MM 500PCS	
2025	Supercap-Solo Bobina 6,7MM 500PCS	
375	Hawe Adapt Matrices	76110481000033GE
376	Hawe Adapt Matrices	
377	Hawe Adapt Matrices	
378	Hawe Adapt Matrices	
379	Hawe Adapt Matrices	
380	Hawe Adapt Matrices	
382	Hawe Adapt Matrices	
390	Hawe Precontoured Matrices	76110481000034GG
391	Hawe Precontoured Matrices	
392	Hawe Precontoured Matrices	
393	Hawe Precontoured Matrices	
394	Hawe Precontoured Matrices	
395	Hawe Precontoured Matrices	
1201	Hawe Matrices Super-Thin 0,038 MM	76110481000035GJ
1202	Hawe Matrices Super-Thin 0,038 MM	
1203	Hawe Matrices Super-Thin 0,038 MM	
1204	Hawe Matrices Super-Thin 0,038 MM	
1205	Hawe Matrices Super-Thin 0,038 MM	
1206	Hawe Matrices Super-Thin 0,038 MM	

1207	Hawe Matrices Super-Thin 0,038 MM	
1208	Hawe Matrices Super-Thin 0,038 MM	
1501	Hawe Titanium Matrices	76110481000036GL
1502	Hawe Titanium Matrices	
1506	Hawe Titanium Matrices	
1507	Hawe Titanium Matrices	
1590	Hawe Contoured Titanium Matrices (30 EA)	76110481000037GN
1591	Hawe Contoured Titanium Matrices (30 EA)	
1001 C	Hawe Contoured Tofflemire Bands, 0.05 Mm	
1001/30	Hawe Tofflemire Matrices	76110481000038GQ
1002/30	Hawe Tofflemire Matrices	
1003/30	Hawe Tofflemire Matrices	
1013/30	Hawe Tofflemire Matrices	
1015/30	Hawe Tofflemire Matrices	
1101 C	Tofflemire Contoured Matrices	76110481000039GS
1101/30	Hawe Tofflemire Matrices 0.038	76110481000040GB
1102/30	Hawe Tofflemire Matrices 0.038	
1103/30	Hawe Tofflemire Matrices 0.038	
1113/30	Hawe Tofflemire Matrices 0.038	
1115/30	Hawe Tofflemire Matrices 0.038	
2750	Hawe Blue Adapt Sectional Matrix Kit	76110481000041GD