

Declaration of Conformity



Legal Manufacturer:
 Ortho-Medical GmbH
 Hauptstrasse 5, 78589 Duerbheim
 SRN: DE-MF-000019971
 Basic UDI-DI: 4065755Z01CL

We herewith declare by our own responsibility, that our Medical Devices related to the Product Group Cast-Cutting have been classified according MDR 2017/745, Annex VII Rule 1, 13

As **Class I**



and have been manufactured under consideration of
Medical Device Regulation 2017/745

The listed products below are conforming to the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS of the Medical Device

Regulation 2017/745 Annex I and are therefore placed into the market and **CE** marked by us.

The conformity assessment of the devices according to MDR 2017/745, Annex IV has been performed under our sole responsibility.

Signatures:

	
--	---

Dietmar Kapp, CEO
 Name, Function

Duerbheim, 2023.05.04
 Place, Date

Thomas Kupferschmid, PRRC
 Name, Function

Part# / REF	Description 1	Description 2	UDI-DI /GTIN	GMDN	CND/ EMDN	UMDNS
01-269.14	Universal Bandage Scissors 14.5 cm,	with plastic handles	04065755003702	46314	Z12139099	13-481
01-269.16	Universal Bandage Scissor 16 cm,	with plastic handle	04065755003719	46314	Z12139099	13-481
01-269.18	Universal Bandage Scissor 18 cm,	with plastic handles	04065755003726	46314	Z12139099	13-481
01-273.17	Smith Scissors, 17,5 cm		04065755003733	46314	Z12139099	13-481
01-279.09	Lister Bandage Scissors angeled, 9 cm		04065755003771	46314	Z12139099	13-481
01-279.11	Lister Bandage Scissors angeled, 11 cm		04065755003788	46314	Z12139099	13-481
01-279.14	Lister Bandage Scissors angeled, 14 cm		04065755003795	46314	Z12139099	13-481
01-279.15	Lister Bandage Scissors angeled,15.5cm		04065755003801	46314	Z12139099	13-481
01-279.18	Lister Bandage Scissors angeled, 18 cm		04065755003818	46314	Z12139099	13-481
01-279.20	Lister Bandage Scissors angeled, 20 cm		04065755003825	46314	Z12139099	13-481
01-281.18	Lister Bandage Scissors,18,5cm	large ringhandle	04065755003832	46314	Z12139099	13-481
01-281.21	Lister Bandage Scissors, 21 cm	large ringhandle	04065755003849	46314	Z12139099	13-481
01-282.16	Lister-Excentric Scissors,16cm		04065755003856	46314	Z12139099	13-481
01-282.19	Lister-Excentric Scissors,19cm		04065755003863	46314	Z12139099	13-481
01-283.20	Esmarch Scissors, 20 cm		04065755003870	46314	Z12139099	13-481
01-283.22	Esmarch Scissors, 22 cm		04065755003887	46314	Z12139099	13-481
01-284.23	Bergmann Scissors, 23 cm		04065755003894	46314	Z12139099	13-481
01-285.23	Lorenz Scissors, 23 cm		04065755003900	46314	Z12139099	13-481
01-286.17	Bandage Scissors,17cm,saw edge		04065755003917	46314	Z12139099	13-481
01-287.18	Lange Scissors, 18 cm		04065755003924	46314	Z12139099	13-481
01-288.24	Bruns Bandage Scissor, 24 cm, smooth		04065755003931	46314	Z12139099	13-481
01-290.18	Smith (Mod. USA) Scissors,18cm		04065755003955	46314	Z12139099	13-481
01-290.20	Smith (Mod. USA) Scissors,20cm		04065755003962	46314	Z12139099	13-481
01-290.23	Smith (Mod. USA) Scissors,23cm		04065755003979	46314	Z12139099	13-481
01-293.14	Knowles Scissors, 14 cm		04065755003986	46314	Z12139099	13-481

Revision	created on	by:	last changed on:	by	Page
1	05.04.2023	D. Boxem	N/A	N/A	1 from 2

Declaration of Conformity



Part# / REF	Description 1	Description 2	UDI-DI /GTIN	GMDN	CND/ EMDN	UMDNS
01-294.14	Knowles Scissors, 14 cm		04065755003993	46314	Z12139099	13-481
01-296.20	Cast Scissors, 20 cm, serrated		04065755004013	46314	Z12139099	13-481
01-297.23	Seutin Cast Scissors, 23 cm		04065755004020	46314	Z12139099	13-481
01-302.24	Stille Plaster Shear, 24 cm		04065755004068	46314	Z12139099	13-481
01-303.23	Stille plaster cast shear, 23 cm		04065755004075	46314	Z12139099	13-481
01-303.26	Stille plaster cast shear, 26 cm		04065755004082	46314	Z12139099	13-481
01-303.37	Stille plaster cast shear, 37 cm		04065755004099	46314	Z12139099	13-481
02-053.18	TC Lister Scissors, 18 cm		04065755005058	46314	Z12139099	13-481
06-206.23	Mod. USA Plaster Spreader 23 cm		04065755103938	13708	Z12139099	13-708
06-206.28	HENNING Cast-, Plaster Spreader, 28 cm		04065755072791	13708	Z12139099	13-708
95-460.100	Spare Screw for Plaster Saw 220V	(95-460.22)	04065755102436	16340	Z12139005	16-340
95-460.101	Screw Fixation for Plaster Saw 220V	(95-460.101)	04065755102443	16340	Z12139005	16-340
95-460.11	Electric Plaster Saw, complete, 110 V		04065755034799	16340	Z12139005	16-340
95-460.12	Saw Blade only, 50 mm diam.		04065755161174	16340	Z12139005	16-340
95-460.13	Saw Blade only, 65 mm diam.		04065755161181	16340	Z12139005	16-340
95-460.14	Round Saw Blade for Plaster Casts,	Ø 50 mm, for Electric Plaster Saw	04065755034805	16340	Z12139005	16-340
95-460.15	Round Saw Blade for Plaster Casts,	Ø 65 mm, for Electric Plaster Saw	04065755034812	16340	Z12139005	16-340
95-460.16	Open End Wrenches 11mm, 2 pieces,	for Plaster Saw, Chrome-Vanadium	04065755034829	16340	Z12139005	16-340
95-460.18	ESMARCH Plaster Knife 18cm	solid handle	04065755106281	35140	Z12139099	12-251
95-460.19	Round Saw Blade for Synthetic-Dressings	special hardened, Ø 50 mm	04065755041490	16340	Z12139005	16-340
95-460.20	Round Saw Blade for Synthetic-Dressings	special hardened, Ø 65 mm	04065755041506	16340	Z12139005	16-340
95-460.22	Plaster Saw oscillating, complete 220V	incl. 2 saw blades diam. 50 + 65 mm	04065755034782	16340	Z12139005	16-340
95-460.25	Vacuum System complete for Plaster Saw	including Plaster Saw 95-460.22, 230V	04065755103334	16340	Z12139005	16-340
95-460.25SET	Vacuum System complete for Plaster Saw	including Plaster Saw 95-460.22	04065755157047	16340	Z12139005	16-340
95-460.26	Hanging kit w.handle, height adjustable	for 95-460.25, 95-460.27, 95-460.28	04065755105635	46314	Z12139099	13-481
95-460.27	Vacuum System complete for Plaster Saw	including Plaster Saw 95-460.11	04065755106472	16340	Z12139005	16-340
95-460.28	Vacuum System complete for Plaster Saw	upgrade set	04065755107158	16340	Z12139005	16-340
95-460.29	Magnetic Plate	for plaster saw with hanging kit	04065755108506	46314	Z12139099	13-481
95-460.30	Plastic Case for Plaster Saw 95-460.22		04065755102986	16340	Z12139005	16-340
95-460.31	Paper Filter Bags for Vacuum Cleaner	packaging unit = 5 pcs.	04065755107356	46314	Z12139099	13-481
95-460.32	Wet Filter Bags for Vacuum Cleaner	packaging unit = 5 pcs.	04065755145464	16340	Z12139005	16-340
95-460.52	HOPKINS Plaster Knife 20cm		04065755093420	35140	Z12139099	12-251
95-460.53	REINER Plaster Knife 20cm		04065755145747	35140	Z12139099	12-251
95-460.70	Flexible and robust tube complete, 2m		04065755145471	16340	Z12139005	16-340
95-460.71	ECO-Flat Folding Filter	for model series < 05/2010	04065755141183	16340	Z12139005	16-340
95-460.72	ECO Fleece Filter	for model series > 06/2010	04065755141206	46314	Z12139099	13-481
95-460.73	ECO-Flat Folding Filter, HEPA	for model series < 05/2010	04065755145488	16340	Z12139005	16-340
95-460.74	ECO Fleece Filter, HEPA	for model series > 06/2010	04065755145495	16340	Z12139005	16-340
95-460.75	Filter Basket		04065755141213	46314	Z12139099	13-481
95-460.76	Engine guard filter		04065755141220	46314	Z12139099	13-481

Stamp.



Duerbbheim, 2023.05.04

End of Declaration.

Revision	created on	by:	last changed on:	by	Page
1	05.04.2023	D. Boxem	N/A	N/A	2 from 2