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EG-Konformitätserklärung

gemäß Anhang VII der Richtlinie 93/42/EWG über Medizinprodukte

EC Declaration of conformity

according to annex VII of the Council Directive 93/42/EEC on medical devices

Wir, KARL HAMMACHER GMBH, erklären in alleiniger Verantwortung, daß die Produkte:
We, KARL HAMMACHER GMBH, declare under our sole responsibility that the products:

Chirurgisch invasive Scheren

wie in der Technischen Dokumentation Nr. 4 gelistet und beschrieben

Surgically invasive Scissors

as listed and described in Technical Documentation No. 4

Basis-UDI-DI <i>Basic UDI-DI</i>	UMDNS Code	Produktgruppe <i>Product group</i>	Risikoklasse <i>Risk class</i>	Regel <i>rule</i>
4049493DENT34003000XM	13-502	Nahtscheren Suture scissors	I	6
4049493DENT34004000XU	15-245	Scheren, chirurgisch Tissue scissors	I	6
4049493DENT34005000Y3	15-245	Zahnfleischscheren Gum scissors	I	6

den Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entsprechen.
meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.

Liste der betroffenen Produkte siehe Anhang.
See appendix for list of affected products.

Diese Konformitätserklärung verfällt spätestens am 27.05.2024.
This Declaration of Conformity will expire on 2024-05-27 at the latest.

Single Registration Number (SRN): <i>Single Registration Number (SRN):</i>	DE-MF-000005099
Konformitätsbewertungsverfahren: <i>Conformity Assessment Procedure:</i>	Anhang VII <i>Annex VII</i>
Benannte Stelle, Name: <i>Notified Body, name:</i>	./.
Benannte Stelle, Kennnummer: <i>Notified Body, identification number:</i>	./.
Kennzeichnung der ausgestellten Bescheinigung(en): <i>Identification of the certificate(s) issued:</i>	./.
Name des Unterzeichners: <i>Name of the person who signed:</i>	Thorsten Hammacher
Funktion des Unterzeichners: <i>Function of the person who signed:</i>	Für die Einhaltung der Regulierungsvorschriften verantwortliche Person (Artikel 15, MDR) <i>Person responsible for regulatory compliance (Article 15, MDR)</i>
Ort der Ausstellung: <i>Place of issue:</i>	Solingen, Germany
Datum der Ausstellung: <i>Date of issue:</i>	2021-05-25



 Thorsten Hammacher

Anhang: Liste der betroffenen Produkte
Appendix: List of affected products

Basis-UDI-DI	ArtNo	UDI-DI	Produkt
4049493DENT34003000XM	HSB 281-09	04049493005525	Naht- und Ligaturschere, Martin-Northbent, seitwärts gebogen, 90 mm Suture and ligature scissors, Martin-Northbent, curved sideways, 90mm
4049493DENT34003000XM	HSB 284-09	04049493005549	Naht- und Ligaturschere, Spencer, gerade, 90 mm Suture and ligature scissors, Spencer, straight, 90 mm
4049493DENT34003000XM	HSB 286-12	04049493005556	Naht- und Ligaturschere, Spencer gerade, 115 mm Suture and ligature scissors, Spencer, straight, 115 mm
4049493DENT34003000XM	HSB 287-11	04049493005563	Naht- und Ligaturschere, Spencer, abgewinkelt, 110 mm Suture and ligature scissors, Spencer, angled, 115 mm
4049493DENT34004000XU	HSB 046-11	04049493004818	Präparierschere, fein, gerade, spitz mit Knopf, 115 mm Dissecting scissors, fine, straight, sharp with knob, 115 mm
4049493DENT34004000XU	HSB 064-14	04049493053793	Schere, Mayo, gerade, stumpf/stumpf, 140 mm Scissors, Mayo, straight, blunt/blunt, 140 mm
4049493DENT34004000XU	HSB 065-14	04049493053809	Schere, Mayo, gebogen, stumpf/stumpf, 140 mm Scissors, Mayo, curved, blunt/blunt, 140 mm
4049493DENT34004000XU	HSB 068-17	04049493053816	Schere, Mayo, gerade, stumpf/stumpf, 170 mm Scissors, Mayo, straight, blunt/blunt, 170 mm
4049493DENT34004000XU	HSB 069-17	04049493053823	Schere, Mayo, gebogen, stumpf/stumpf, 170 mm Scissors, Mayo, curved, blunt/blunt, 170 mm
4049493DENT34004000XU	HSB 070-11	04049493004986	Schere, Standard, gerade, stumpf/stumpf, 115 mm Standard scissors, straight, blunt/blunt, 115 mm
4049493DENT34004000XU	HSB 072-13	04049493005006	Schere, Standard, gerade, stumpf/stumpf, 130 mm Standard scissors, straight, blunt/blunt, 130 mm
4049493DENT34004000XU	HSB 074-14	04049493005020	Schere, Standard, gerade, stumpf/stumpf, 145 mm Standard scissors, straight, blunt/blunt, 145 mm
4049493DENT34004000XU	HSB 076-15	04049493005044	Schere, Standard, gerade, stumpf/stumpf, 155 mm Standard scissors, straight, blunt/blunt, 155 mm
4049493DENT34004000XU	HSB 078-16	04049493005068	Schere, Standard, gerade, stumpf/stumpf, 165 mm Standard scissors, straight, blunt/blunt, 165 mm
4049493DENT34004000XU	HSB 080-18	04049493005082	Schere, Standard, gerade, stumpf/stumpf, 185 mm Standard scissors, straight, blunt/blunt, 185 mm
4049493DENT34004000XU	HSB 084-11	04049493005105	Schere, Standard, gerade, spitz/stumpf, 115 mm Standard scissors, straight, sharp/blunt, 115 mm
4049493DENT34004000XU	HSB 086-13	04049493005129	Schere, Standard, gerade, spitz/stumpf, 130 mm Standard scissors, straight, sharp/blunt, 130 mm
4049493DENT34004000XU	HSB 088-14	04049493005143	Schere, Standard, gerade, spitz/stumpf, 145 mm Standard scissors, straight, sharp/blunt, 145 mm
4049493DENT34004000XU	HSB 090-15	04049493005167	Schere, Standard, gerade, spitz/stumpf, 155 mm Standard scissors, straight, sharp/blunt, 155 mm
4049493DENT34004000XU	HSB 092-16	04049493005181	Schere, Standard, gerade, spitz/stumpf, 165 mm Standard scissors, straight, sharp/blunt, 165 mm
4049493DENT34004000XU	HSB 094-18	04049493005204	Schere, Standard, gerade, spitz/stumpf, 185 mm Standard scissors, straight, sharp/blunt, 185 mm
4049493DENT34004000XU	HSB 098-11	04049493005228	Schere, Standard, gerade, spitz/spitz, 115 mm Standard scissors, straight, sharp/sharp, 115 mm
4049493DENT34004000XU	HSB 100-13	04049493005242	Schere, Standard, gerade, spitz/spitz, 130 mm Standard scissors, straight, sharp/sharp, 130 mm
4049493DENT34004000XU	HSB 102-14	04049493005266	Schere, Standard, gerade, spitz/spitz, 145 mm Standard scissors, straight, sharp/sharp, 145 mm
4049493DENT34004000XU	HSB 104-15	04049493005280	Schere, Standard, gerade, spitz/spitz, 155 mm Standard scissors, straight, sharp/sharp, 155 mm
4049493DENT34004000XU	HSB 106-16	04049493005303	Schere, Standard, gerade, spitz/spitz, 165 mm Standard scissors, straight, sharp/sharp, 165 mm
4049493DENT34004000XU	HSB 108-18	04049493005334	Schere, Standard, gerade, spitz/spitz, 185 mm Standard scissors, straight, sharp/sharp, 185 mm
4049493DENT34004000XU	HSB 120-14	04049493005396	Präparierschere, Baby-Metzenbaum, gerade, stumpf/stumpf, 145 mm Dissecting scissors, Baby-Metzenbaum, straight, sharp/sharp, 145 mm
4049493DENT34004000XU	HSB 121-14	04049493005402	Präparierschere, Baby-Metzenbaum, gebogen, stumpf/stumpf, 145 mm Dissecting scissors, Baby-Metzenbaum, curved, blunt/blunt, 145 mm
4049493DENT34004000XU	HSB 126-14	04049493005457	Präparierschere, Metzenbaum-Fino, gerade, spitz/spitz, 145 mm Dissecting scissors, Metzenbaum-Fino, straight, sharp/sharp, 145 mm
4049493DENT34004000XU	HSB 127-14	04049493005464	Präparierschere, Metzenbaum-Fino, gebogen, spitz/spitz, 145 mm Dissecting scissors, Metzenbaum-Fino, curved, sharp/sharp, 145 mm
4049493DENT34004000XU	HSB 128-18	04049493005471	Präparierschere, Metzenbaum-Fino, gerade, spitz/spitz, 180 mm Dissecting scissors, Metzenbaum-Fino, straight, sharp/sharp, 180 mm
4049493DENT34004000XU	HSB 129-18	04049493005488	Präparierschere, Metzenbaum-Fino, gebogen, spitz/spitz, 180 mm Dissecting scissors, Metzenbaum-Fino, curved, sharp/sharp, 180 mm
4049493DENT34004000XU	HSB 138-14	04049493005518	Inzisionsschere, geknöpft, gerade, 145 mm Incision scissors, probe tip, straight, 145 mm

Basis-UDI-DI	ArtNo	UDI-DI	Produkt
4049493DENT34004000XU	HSB 556-18	04049493056503	Mikroschere, gerade, Rundgriff, 180 mm Micro-scissors, straight, round handle, 180 mm
4049493DENT34004000XU	HSB 557-18	04049493056404	Mikroschere, gebogen, Rundgriff, 180 mm Micro-scissors, curved, round handle, 180 mm
4049493DENT34005000Y3	HSB 002-09	04049493004443	Schere, fein, gerade, 90 mm Scissors, fine, straight, 90 mm
4049493DENT34005000Y3	HSB 003-09	04049493004450	Schere, fein, gebogen, 90 mm Scissors, fine, curved, 90 mm
4049493DENT34005000Y3	HSB 004-09	04049493004467	Schere, Gradle, sehr fein, gebogen, 95 mm Scissors, Gradle, extra fine, curved, 95 mm
4049493DENT34005000Y3	HSB 005-09	04049493004474	Schere, Gradle, sehr fein, gebogen, 95 mm Scissors, Gradle, extra fine, curved, 95 mm
4049493DENT34005000Y3	HSB 006-10	04049493004481	Schere, fein, gerade, spitz/spitz, 105 mm Scissors, fine, straight, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 007-10	04049493004498	Schere, fein, gebogen, spitz/spitz, 105 mm Scissors, fine, curved, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 008-13	04049493004504	Anatomische Schere, gerade, spitz/spitz, 130 mm Anatomical scissors, straight, sharp/sharp, 130 mm
4049493DENT34005000Y3	HSB 010-10	04049493004528	Schere, fein, gerade, spitz/spitz, 105 mm Scissors, fine, straight, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 011-10	04049493004535	Schere, fein, gebogen, spitz/spitz, 105 mm Scissors, fine, curved, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 012-11	04049493004542	Schere, fein, gerade, spitz/spitz, 125 mm Scissors, fine, straight, sharp/sharp, 125 mm
4049493DENT34005000Y3	HSB 013-11	04049493004559	Schere, fein, gebogen, spitz/spitz, 125 mm Scissors, fine, curved, sharp/sharp, 125 mm
4049493DENT34005000Y3	HSB 0140-11	04049493004566	Schere, SUPER-CUT, gerade, spitz/spitz, 115 mm Scissors, SUPER-CUT, straight, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 014-11	04049493004573	Schere gerade, spitz/spitz, 115 mm Scissors, straight, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 0141-11	04049493004580	Schere, SUPER-CUT, gebogen, spitz/spitz, 115 mm Scissors, SUPER-CUT, curved, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 015-11	04049493004597	Schere, gebogen, spitz/spitz, 115 mm Scissors, curved, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 019-11	04049493004634	Schere, fein, abgewinkelt, spitz/spitz, 115 mm Scissors, fine, angled, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 020-11	04049493004641	Schere, sehr fein, gerade, spitz/spitz, 115 mm Scissors, extra fine, straight, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 021-11	04049493004658	Schere, sehr fein, gebogen, spitz/spitz, 115 mm Scissors, extra fine, curved, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 022-12	04049493004665	Schere, Wagner, gerade, spitz/spitz, 120 mm Scissors, Wagner, straight, sharp/sharp, 120 mm
4049493DENT34005000Y3	HSB 023-12	04049493004672	Schere, Wagner, gebogen, spitz/spitz, 120 mm Scissors, Wagner, curved, sharp/sharp, 120 mm
4049493DENT34005000Y3	HSB 028-15	04049493004696	Schere, Joseph, gerade, spitz/spitz, 140 mm Scissors, Joseph, straight, sharp/sharp, 140 mm
4049493DENT34005000Y3	HSB 029-15	04049493004702	Schere, Joseph, gebogen, spitz/spitz, 140 mm Scissors, Joseph, curved, sharp/sharp, 140 mm
4049493DENT34005000Y3	HSB 030-16	04049493004719	Schere, Kelly, gerade, spitz/spitz, 160 mm Scissors, Kelly, straight sharp/sharp, 160 mm
4049493DENT34005000Y3	HSB 031-16	04049493004726	Schere, Kelly, gebogen, spitz/spitz, 160 mm Scissors, Kelly, curved sharp/sharp, 160 mm
4049493DENT34005000Y3	HSB 036-10	04049493053786	Zahnfleischschere, gerade, spitz/spitz, 105 mm Gum scissors, straight, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 039-16	04049493004771	Zahnfleischschere, Locklin, gezahnt, 160 mm Gum scissors, Locklin, serrated, 160 mm
4049493DENT34005000Y3	HSB 041-17	04049493004788	Zahnfleischschere, Dean, gebogen, gezahnt, 170 mm Gum scissors, Dean, curved, serrated, 170 mm
4049493DENT34005000Y3	HSB 047-11	04049493004825	Schere, La Grange, doppelt gebogen, gezahnt, spitz/spitz, 115 mm Scissors, La Grange, double curved, serrated, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 048-13	04049493004832	Zahnfleischschere, Goldman-Fox, gerade, spitz/spitz, gezahnt, 130 mm Gum scissors, Goldman-Fox, straight, sharp/sharp, serrated, 130 mm
4049493DENT34005000Y3	HSB 049-13	04049493004849	Zahnfleischschere, Goldman-Fox, gebogen, spitz/spitz, gezahnt, 130 mm Gum scissors, Goldman-Fox, curved, sharp/sharp, serrated, 130 mm
4049493DENT34005000Y3	HSB 300-11	04049493005587	Zahnfleischschere, TC, gerade, spitz/spitz, 115 mm Gum scissors, TC, straight, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 301-11	04049493005594	Zahnfleischschere, TC, gebogen, spitz/spitz, 115 mm Gum scissors, TC, curved, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 302-13	04049493005600	Präparierschere, Goldman-Fox, TC, gerade, spitz/spitz, 130 mm Gum scissors, Goldman-Fox, TC, straight, sharp/sharp, 130 mm

Basis-UDI-DI	ArtNo	UDI-DI	Produkt
4049493DENT34005000Y3	HSB 303-13	04049493005617	Präparierschere, Goldman-Fox, TC, gebogen, spitz/spitz, 130 mm Gum scissors, Goldman-Fox, TC, curved, sharp/sharp, 130 mm
4049493DENT34005000Y3	HSB 310-14	04049493005662	Schere, chirurgisch, Standard, TC, gerade, spitz/stumpf, 145 mm Scissors, surgical, standard, TC, straight, sharp/blunt, 145 mm
4049493DENT34005000Y3	HSB 314-14	04049493005686	Schere, chirurgisch, Standard, TC, gerade, spitz/spitz, 145 mm Scissors, surgical, standard, TC, straight, sharp/sharp, 145 mm
4049493DENT34005000Y3	HSB 390-10	04049493005914	Präparierschere, SUPER-CUT, gerade, spitz/spitz, 105 mm Dissecting scissors, SUPER-CUT, straight, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 391-10	04049493005938	Präparierschere, SUPER-CUT, gebogen, spitz/spitz, 105 mm Dissecting scissors, SUPER-CUT, curved, sharp/sharp, 105 mm
4049493DENT34005000Y3	HSB 392-11	04049493005952	Schere, La Grange, SUPER-CUT, S-förmig gebogen, spitz/spitz, 115 mm Scissors, La Grange, SUPER-CUT, S-curved, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 393-11	04049493005976	Zahnfleischschere, SUPER-CUT, abgewinkelt, spitz/spitz, 105 mm Gum scissors, SUPER-CUT, angled, sharp/sharp, 115 mm
4049493DENT34005000Y3	HSB 394-13	04049493005983	Gingivektomie-Schere, Goldman-Fox, SUPER-CUT, S-förmig gebogen, gezahnt, 130 mm Gingivectomy scissors, Goldman-Fox, SUPER-CUT, S-shaped, serrated, 130 mm
4049493DENT34005000Y3	HSB 396-13	04049493006010	Schere, grazil, SUPER-CUT, gerade, spitz/stumpf, 130 mm Scissors, gracile, SUPER-CUT, straight, sharp/blunt, 130 mm
4049493DENT34005000Y3	HSB 400-14	04049493006058	Schere, Joseph, SUPER-CUT, gerade, spitz/spitz, 140 mm Scissors, Joseph, SUPER-CUT, straight, sharp/sharp, 140 mm
4049493DENT34005000Y3	HSB 401-14	04049493006065	Schere, Joseph, SUPER-CUT, gebogen, spitz/spitz, 140 mm Scissors, Joseph, SUPER-CUT, curved, sharp/sharp, 140 mm
4049493DENT34005000Y3	HSB 402-16	04049493006096	Schere, Kelly, SUPER-CUT, gerade, spitz/spitz, 160 mm Scissors, Kelly, SUPER-CUT, straight, sharp/sharp, 160 mm
4049493DENT34005000Y3	HSB 403-16	04049493006102	Schere, Kelly, SUPER-CUT, gebogen, spitz/spitz, 160 mm Scissors, Kelly, SUPER-CUT, curved, sharp/sharp, 160 mm
4049493DENT34005000Y3	HSB 412-13	04049493006119	Schere, Standard, SUPER-CUT, gerade, spitz/stumpf, 130 mm Standard scissors, SUPER-CUT, straight, sharp/blunt, 130 mm
4049493DENT34005000Y3	HSB 422-13	04049493006157	Schere, Standard, SUPER-CUT, gerade, spitz/spitz, 130 mm Standard scissors, SUPER-CUT, straight, sharp/sharp, 130 mm
4049493DENT34005000Y3	HSB 423-13	04049493006164	Schere, Standard, SUPER-CUT, gebogen, spitz/spitz, 130 mm Standard scissors, SUPER-CUT, curved, sharp/sharp, 130 mm
4049493DENT34005000Y3	HSB 500-09	04049493006287	Mikroschere, gerade, 90 mm, 10 mm Schnittlänge Micro-scissors, straight, 90 mm, 10 mm cutting length
4049493DENT34005000Y3	HSB 504-10	04049493006300	Mikroschere, gerade, 105 mm, 15 mm Schnittlänge Micro-scissors, straight, 105 mm, 15 mm cutting length
4049493DENT34005000Y3	HSB 515-09	04049493006362	Mikroschere, abgewinkelt, 90 mm, 10 mm Schnittlänge Micro-scissors, angled, 90 mm, 10 mm cutting length
4049493DENT34005000Y3	HSB 516-09	04049493006379	Mikroschere, gerade, 90 mm Micro-scissors, straight, 90 mm
4049493DENT34005000Y3	HSB 520-12	04049493006409	Mikroschere, Noyes, gerade, 120 mm, 12 mm Schnittlänge Micro-scissors, Noyes, straight, 120 mm, 12 mm cutting length
4049493DENT34005000Y3	HSB 554-14	04049493006652	Mikroschere, gerade, Rundgriff, 140 mm Micro-scissors, straight, round handle, 140 mm
4049493DENT34005000Y3	HSB 555-14	04049493006669	Mikroschere, gebogen, Rundgriff, 140 mm Micro-scissors, curved, round handle, 140 mm
4049493DENT34005000Y3	HWB 002-11	04049493040946	Schere, gerade, spitz/spitz, 110 mm Scissors, straight, sharp/sharp, 110 mm
4049493DENT34005000Y3	HWB 003-11	04049493040953	Schere, gebogen, spitz/spitz, 110 mm Scissors, curved, sharp/sharp, 110 mm
4049493DENT34005000Y3	HWB 005-11	04049493040960	Schere, stark gebogen, spitz/spitz, 110 mm Scissors, strongly curved, sharp/sharp, 110 mm
4049493DENT34005000Y3	HWB 010-11	04049493040991	Schere, gerade, spitz/stumpf, 110 mm Scissors, straight, sharp/blunt, 110 mm
4049493DENT34005000Y3	HWB 022-11	04049493041066	Schere, Stevens, gerade, besonders feine Spitze, 110 mm Scissors, Stevens, straight, extra fine tip, 110 mm
4049493DENT34005000Y3	HWB 040-13	04049493041141	Schere, gerade, spitz/stumpf, 130 mm Scissors, straight, sharp/blunt, 130 mm
4049493DENT34005000Y3	HWB 041-13	04049493041158	Schere, gebogen, spitz/stumpf, 130 mm Scissors, curved, sharp/blunt, 130 mm
4049493DENT34005000Y3	HWB 042-14	04049493041165	Schere, gerade, spitz/stumpf, 145 mm Scissors, straight, sharp/blunt, 145 mm
4049493DENT34005000Y3	HWB 043-14	04049493041172	Schere, gebogen, spitz/stumpf, 145 mm Scissors, curved, sharp/blunt, 145 mm
4049493DENT34005000Y3	HWB 044-16	04049493041189	Schere, gerade, spitz/stumpf, 160 mm Scissors, straight, sharp/blunt, 160 mm
4049493DENT34005000Y3	HWB 045-16	04049493041196	Schere, gebogen, spitz/stumpf, 160 mm Scissors, curved, sharp/blunt, 160 mm

Basis-UDI-DI	ArtNo	UDI-DI	Produkt
4049493DENT34005000Y3	HWB 050-13	04049493041202	Schere, gerade, spitz/spitz, 130 mm Scissors, straight, sharp/sharp, 130 mm
4049493DENT34005000Y3	HWB 052-14	04049493041226	Schere, gerade, spitz/spitz, 145 mm Scissors, straight, sharp/sharp, 145 mm
4049493DENT34005000Y3	HWB 054-16	04049493041240	Schere, gerade, spitz/spitz, 160 mm Scissors, straight, sharp/sharp, 160 mm