









 Medical products in motion	DoC	Dok. DMF 005-011-002 Version 3
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Hersteller / Manufacturer


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erklärt in alleiniger Verantwortung, dass das Medizinprodukt		declares under our sole responsibility that the medical product		
Manipulierkopf/Trial-Head Ø22.2mm  Bipolar-Probekopf Ø 22/28 mm 	Manipulierkopf/Trial-Head Ø28mm  Bipolar Einsetzinstrument gebogen 	Manipulierkopf/Trial-Head Ø32mm  Bipolar Einsetzinstrument gerade 	Manipulierkopf/Trial-Head Ø 36mm  Bipolar Einsetzinstrument gerade 	Manipulierkopf/Trial-Head Ø40mm  Repositionszange 
zur zementfreien Implantation der Kugelkopf und der Bipolar Kopf,		for the cementless implantation of Ballhead and Bipolar Head,		
den einschlägigen Bestimmungen des Anhangs II der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 in der Fassung vom 21. September 2007 über Medizinprodukte entspricht.		meets the provisions of annex II of the Council Directive 93/42/EEC of June 14th , 1993 in the version of 21st of September 2007 concerning medical devices which apply to it.		
Nach Anhang IX Regel 6 der Richtlinie handelt es sich um ein Medizinprodukt der Klasse IIa.		According annex IX rule 6 the guideline they are Class IIa medical devices.		
Konformitätsbewertungsverfahren nach Anhang II.1-3, 5 (ohne Abschnitt 4) der Richtlinie 93/42/EWG. Die Grundlegenden Anforderungen gemäss Anhang 1 der Richtlinie 93/42/EWG werden erfüllt.		Conformity valuation procedure according to appendix II.1-3, 5 (without chapter 4) of the Directive 93/42/EEC. The essential requirements in acc. with annex I of guideline 93/42/EEC are met.		
Angewandte harmonisierte Normen:		Applied harmonized standards:		
EN ISO 13485:2016 / EN ISO 14971:2012 / EN ISO 16061:2015 / EN ISO 10993-1:2009 / EN ISO 17664:2017 / EN ISO 17665-1:2006 / EN ISO 15223-1:2016 / EN 1041:2008				
Benannte Stelle: SQS, Schweizerische Vereinigung für Qualitäts- und Management- Systeme, CH-3052 Zollikofen, CE1250		Notified Body: SQS, Swiss Association for Quality and Management Systems, CH-3052 Zollikofen, CE1250		

Inkraftsetzung / Activation: 27. April 2020
 Gültig bis / Duration of validity: 25. Mai 2024
 Ort, Datum / Place, Date: Zürich, 20. Mai 2020



 Thomas Kuoni, CEO

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Anlage I / Annex I

Diese Konformitätserklärung ist gültig für die folgenden Medizinprodukte:
This Declaration of Conformity is valid for the following Medical Devices:


REF Nummer/Number	Medical Devices Benennung DE	Medical Devices Description EN
60.22.12	Manipulierkopf Ø 22mm M	Trial-Head Ø 22mm M
60.22.13	Manipulierkopf Ø 22mm L	Trial-Head Ø 22mm L
60.28.11	Manipulierkopf Ø 28mm S	Trial-Head Ø 28mm S
60.28.12	Manipulierkopf Ø 28mm M	Trial-Head Ø 28mm M
60.28.13	Manipulierkopf Ø 28mm L	Trial-Head Ø 28mm L
60.28.14	Manipulierkopf Ø 28mm XL	Trial-Head Ø 28mm XL
60.28.15	Manipulierkopf Ø 28mm XXL	Trial-Head Ø 28mm XXL
60.32.11	Manipulierkopf Ø 32mm S	Trial-Head Ø 32mm S
60.32.12	Manipulierkopf Ø 32mm M	Trial-Head Ø 32mm M
60.32.13	Manipulierkopf Ø 32mm L	Trial-Head Ø 32mm L
60.32.14	Manipulierkopf Ø 32mm XL	Trial-Head Ø 32mm XL
60.32.15	Manipulierkopf Ø 32mm XXL	Trial-Head Ø 32mm XXL
60.36.11	Manipulierkopf Ø 36mm S	Trial-Head Ø 36mm S
60.36.12	Manipulierkopf Ø 36mm M	Trial-Head Ø 36mm M
60.36.13	Manipulierkopf Ø 36mm L	Trial-Head Ø 36mm L
60.36.14	Manipulierkopf Ø 36mm XL	Trial-Head Ø 36mm XL
60.40.11	Manipulierkopf Ø 40mm S	Trial-Head Ø 40mm S
60.40.12	Manipulierkopf Ø 40mm M	Trial-Head Ø 40mm M
60.40.13	Manipulierkopf Ø 40mm L	Trial-Head Ø 40mm L
60.40.14	Manipulierkopf Ø 40mm XL	Trial-Head Ø 40mm XL

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138.801.01.90	Instrumentenset zur Bipolar Kopf	Instruments tray for Bipolar Head
60.138.00	Repositionszange	Forceps for Bipolar head
60.138.01	Bipolar Einsetzinstrument gerade	Bipolar setting instrument straight
60.138.02	Bipolar Einsetzinstrument gebogen	Bipolar setting instrument bowed
60.138.39	Bipolar Probekopf 39/22 mm	Bipolar trial head 39/22 mm
60.138.40	Bipolar Probekopf 40/22 mm	Bipolar trial head 40/22 mm
60.138.41	Bipolar Probekopf 41/22 mm	Bipolar trial head 41/22 mm
60.138.42	Bipolar Probekopf 42/22 mm	Bipolar trial head 42/22 mm
60.138.43	Bipolar Probekopf 43/28 mm	Bipolar trial head 43/28 mm
60.138.44	Bipolar Probekopf 44/28 mm	Bipolar trial head 44/28 mm
60.138.45	Bipolar Probekopf 45/28 mm	Bipolar trial head 45/28 mm
60.138.46	Bipolar Probekopf 46/28 mm	Bipolar trial head 46/28 mm
60.138.47	Bipolar Probekopf 47/28 mm	Bipolar trial head 47/28 mm
60.138.48	Bipolar Probekopf 48/28 mm	Bipolar trial head 48/28 mm
60.138.49	Bipolar Probekopf 49/28 mm	Bipolar trial head 49/28 mm
60.138.50	Bipolar Probekopf 50/28 mm	Bipolar trial head 50/28 mm
60.138.51	Bipolar Probekopf 51/28 mm	Bipolar trial head 51/28 mm
60.138.52	Bipolar Probekopf 52/28 mm	Bipolar trial head 52/28 mm
60.138.53	Bipolar Probekopf 53/28 mm	Bipolar trial head 53/28 mm

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60.138.54	Bipolar Probekopf 54/28 mm	Bipolar trial head 54/28 mm
60.138.55	Bipolar Probekopf 55/28 mm	Bipolar trial head 55/28 mm
60.138.56	Bipolar Probekopf 56/28 mm	Bipolar trial head 56/28 mm
60.138.57	Bipolar Probekopf 57/28 mm	Bipolar trial head 57/28 mm
60.138.58	Bipolar Probekopf 58/28 mm	Bipolar trial head 58/28 mm
60.138.59	Bipolar Probekopf 59/28 mm	Bipolar trial head 59/28 mm
60.138.60	Bipolar Probekopf 60/28 mm	Bipolar trial head 60/28 mm
60.138.61	Bipolar Probekopf 61/28 mm	Bipolar trial head 61/28 mm
60.138.62	Bipolar Probekopf 62/28 mm	Bipolar trial head 62/28 mm
60.138.63	Bipolar Probekopf 63/28 mm	Bipolar trial head 63/28 mm
60.138.64	Bipolar Probekopf 64/28 mm	Bipolar trial head 64/28 mm
60.138.65	Bipolar Probekopf 65/28 mm	Bipolar trial head 65/28 mm