

Wir, der Hersteller, erklären in alleiniger Verantwortung, dass die unten beschriebenen Produkte den Anforderungen der Richtlinie 93/42/EWG entsprechen. <i>We, the manufacturer, declare in sole responsibility that the products described below meet the requirements of Directive 93/42/EEC.</i>	
Hersteller / <i>manufacturer</i>	OHST Medizintechnik AG Grünauer Fenn 3 D-14712 Rathenow Deutschland / Germany
Produktbezeichnung / <i>Product description</i>	H4.1 Bipolarkopf (Implantatstahl) / <i>H4.1 Bipolar Head (Implant Steel)</i>  H4.2 Bipolarkopf (CoCrMo) / <i>H4.2 Bipolar Head (CoCrMo)<sup>1</sup></i>
Klassifizierung nach RL 93/42/EWG, Anhang IX / <i>Classification according 93/42/EEC, annex IX</i>	Klasse III / <i>class III</i>
Angewandte Normen / <i>Applied standards</i>	FB 4-06 Normenliste / <i>FB 4-06 list of standards</i>
Benannte Stelle / <i>Notified Body</i>	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2, 20355 Hamburg, Germany (MEDCERT Identification No.: 0482)
Konformitätsbewertungsverfahren: Anhang II, Abschnitt 4 der Richtlinie 93/42/EWG des Rates über Medizinprodukte  <i>Conformity assessment procedure: Annex II, section 4 of the Council Directive 93/42/EEC concerning Medical Devices.</i>	Berichts-Nr.: 13434PS12F Verfahrens-Nr.: PP – 13434 Bescheinigungs-Nr.: 13434DE411210120B Gültigkeit der Bescheinigung bis: 22.12.2023  <i>Report No.: 13434FS12F Process No.: PP – 13434 Certificate No.: 13434GB411210120A Certificate is valid until: 22.12.2023</i>

Gültigkeit der Konformitätserklärung bis / *Declaration of Conformity is valid until:* 22.12.2023

Rathenow, 18.02.2021  
Ort, Datum / *place, date*

  
Unterschrift / *signature*

H. Bookhagen / *Regulatory Affairs*  
Name und Funktion / *name and function*

<sup>1</sup> Details siehe „FB 7-58 Liste der konformitätsbewerteten Produkte“ / *Details please check „FB 7-58 list of conforming products“*

UDI-1   UDI-DI	Produkt REF Nr.   Product REF no.	Produktname 1   Device Name 1	Produktname 2   Device Name 2	Produktname 1   Device Name 1	Produktname 2   Device Name 2	Versnrsnr.   Referenz no.	Risikoklasse   Risk class	CE seit   CE since
4250118616389	151-042	Bipolarkefip 042mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 042mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616402	151-044	Bipolarkefip 044mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 044mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616426	151-046	Bipolarkefip 046mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 046mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616440	151-048	Bipolarkefip 048mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 048mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616464	151-050	Bipolarkefip 050mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 050mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616488	151-052	Bipolarkefip 052mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 052mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616501	151-054	Bipolarkefip 054mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 054mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616525	151-056	Bipolarkefip 056mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 056mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616549	151-058	Bipolarkefip 058mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 058mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118616563	151-060	Bipolarkefip 060mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 060mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	01.01.96
4250118641947	150-038	Bipolarkefip 038mm KO 22mm	ISO 5832-4 CoCrMo	Bipolar Head 038mm Head Ø22mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118641954	150-039	Bipolarkefip 039mm KO 22mm	ISO 5832-4 CoCrMo	Bipolar Head 039mm Head Ø22mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118641961	150-040	Bipolarkefip 040mm KO 22mm	ISO 5832-4 CoCrMo	Bipolar Head 040mm Head Ø22mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118641978	150-041	Bipolarkefip 041mm KO 22mm	ISO 5832-4 CoCrMo	Bipolar Head 041mm Head Ø22mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616600	150-042	Bipolarkefip 042mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 042mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616617	150-043	Bipolarkefip 043mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 043mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616624	150-044	Bipolarkefip 044mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 044mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616631	150-045	Bipolarkefip 045mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 045mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616648	150-046	Bipolarkefip 046mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 046mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616655	150-047	Bipolarkefip 047mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 047mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616662	150-048	Bipolarkefip 048mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 048mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616679	150-049	Bipolarkefip 049mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 049mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616686	150-050	Bipolarkefip 050mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 050mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616693	150-051	Bipolarkefip 051mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 051mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616709	150-052	Bipolarkefip 052mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 052mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616716	150-053	Bipolarkefip 053mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 053mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616723	150-054	Bipolarkefip 054mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 054mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616730	150-055	Bipolarkefip 055mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 055mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616747	150-056	Bipolarkefip 056mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 056mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616754	150-057	Bipolarkefip 057mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 057mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616761	150-058	Bipolarkefip 058mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 058mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616778	150-059	Bipolarkefip 059mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 059mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250118616785	150-060	Bipolarkefip 060mm KO 28mm	ISO 5832-4 CoCrMo	Bipolar Head 060mm Head Ø28mm	ISO 5832-4 CoCrMo	H4.2	III	01.01.96
4250816971483	151-039	Bipolarkefip 039mm KO 22mm	ISO 5832-1 Implantstahl	Bipolar Head 039mm Head Ø22mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250816971490	151-040	Bipolarkefip 040mm KO 22mm	ISO 5832-1 Implantstahl	Bipolar Head 040mm Head Ø22mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250816971506	151-041	Bipolarkefip 041mm KO 22mm	ISO 5832-1 Implantstahl	Bipolar Head 041mm Head Ø22mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250118616396	151-043	Bipolarkefip 043mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 043mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250118616419	151-045	Bipolarkefip 045mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 045mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250118616433	151-047	Bipolarkefip 047mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 047mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250118616457	151-049	Bipolarkefip 049mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 049mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
4250118616471	151-051	Bipolarkefip 051mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head 051mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21

UDI-DI UD-DI	Produkt REF Nr.   Product REF no.	Produktname 1   Device Name 1	Produktname 2   Device Name 2	Produktname 1   Device Name 1	Produktname 2   Device Name 2	Verweissnr.   Referenz no.	Risikoklasse   Risk class	CE seit   CE since
42501186165495	151-053	Bipolar Kopf Ø53mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head Ø53mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
42501186165518	151-055	Bipolar Kopf Ø55mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head Ø55mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
42501186165532	151-057	Bipolar Kopf Ø57mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head Ø57mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21
42501186165556	151-059	Bipolar Kopf Ø59mm KO 28mm	ISO 5832-1 Implantstahl	Bipolar Head Ø59mm Head Ø28mm	ISO 5832-1 Implant Steel	H4.1	III	02.02.21

Rathenow, 02.02.2021  
Unterschrift / Signature   
H. Bookhagen / Regulatory Affairs  
[Name und Funktion] / [Name and Function]