

# EC Design Examination Certificate

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the design of the medical device(s):

**Hip Implants  
BioBall™-System and Bipolar Heads  
with specifications listed in the appendix**

of the manufacturer:

**Merete GmbH  
Alt-Lankwitz 102  
12247 Berlin  
Germany**

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

## Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

**This certificate is valid from 31 August 2019 until 27 May 2024**

Report No.: 13053FS11F  
Process No.: PP – 13053  
Certificate No.: 13053GB411190823

Hamburg, 23 August 2019

  
MEDCERT Certification Body  
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010009e EN / Rev. 5 / 2019.05.22



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Design Examination Certificate

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### Specifications

BioBall™ Metal Head						
HM30028	HM30032	HM30033	HM30035	HM30036	HM30038	—

BioBall™ Adapter MS 10/12 Standard						
HM30101	HM30102	HM30103	HM30104	HM30105	HM30106	—

BioBall™ Adapter 12/14 Standard						
HM30121	HM30122	HM30123	HM30124	HM30125	HM30126	HM30127
HM30128	—	—	—	—	—	—

BioBall™ Adapter 14/16 Standard						
HM30142	HM30143	HM30144	HM30145	HM30146	HM30147	HM30148

BioBall™ Adapter MS 10/12 Offset						
HM30202	HM30203	HM30204	HM30205	HM30206	—	—

BioBall™ Adapter 12/14 Offset						
HM30222	HM30223	HM30224	HM30225	HM30226	HM30227	HM30228

BioBall™ Duo Head						
HM30342	HM30343	HM30344	HM30345	HM30346	HM30347	HM30348
HM30349	HM30350	HM30351	HM30352	HM30353	HM30354	HM30355
HM30356	HM30357	HM30358	HM30359	HM30360	HM30362	HM30364

BioBall™ Adapter 14/16 Offset						
HM30445	HM30446	HM30447	HM30448	—	—	—

BioBall™ Adapter MSPC Standard						
HM31132	HM31133	—	—	—	—	—

BioBall™ Adapter MSBG Standard						
HM31142	HM31143	HM31144	HM31145	—	—	—

BioBall™ Adapter MSSR Standard						
HM31152	HM31153	HM31154	—	—	—	—

BioBall™ Adapter Offset II						
HM31222	HM31223	HM31224	HM31225	HM31226	HM31227	HM31228

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<b>BioBall™ Adapter MS 8/10 Standard</b>						
HM32121	HM32122	HM32123	HM32124	HM32125	–	–

  

<b>BioBall™ Adapter MS 8/10 Offset</b>						
HM32222	HM32223	HM32224	HM32225	–	–	–

  

<b>BioBall™ Adapter MSZI</b>						
HM33121	HM33122	HM33123	HM33124	HM33125	HM33126	–

  

<b>BioBall™ Adapter MSV4 Standard</b>						
HM34122	HM34123	HM34124	HM34125	HM34126	–	–

  

<b>BioBall™ Adapter MSV4 Offset</b>						
HM34222	HM34223	HM34224	HM34225	HM34226	–	–

  

<b>BioBall™ MaxiMotion™ PE-Inlay with Metal Head</b>						
HM35046	HM35048	HM35050	HM35052	HM35054	HM35056	HM35058
HM35060	HM35062	HM35064	HM35066	HM35068	–	–

  

<b>BioBall™ MaxiMotion™ XPE-Inlay with Metal Head</b>						
HM35069	HM35070	HM35071	HM35072	HM35073	HM35074	HM35075
HM35076	HM35077	HM35078	HM35079	HM35080	HM35081	HM35082
HM35083	HM35084	HM35085	HM35086	HM35087	HM35088	HM35089

  

<b>BioBall™ MaxiMotion™ Cup cemented</b>						
HM35146	HM35148	HM35150	HM35152	HM35154	HM35156	HM35158
HM35160	HM35162	HM35164	HM35166	HM35168	–	–

  

<b>BioBall™ MaxiMotion™ Cup non-cemented TPS Coating</b>						
HM35246	HM35248	HM35250	HM35252	HM35254	HM35256	HM35258
HM35260	HM35262	HM35264	HM35266	HM35268	–	–

  

<b>BioBall™ MaxiMotion™ Cup non-cemented TPS BONIT® Coating</b>						
HM35346	HM35348	HM35350	HM35352	HM35354	HM35356	HM35358
HM35360	HM35362	HM35364	HM35366	HM35368	–	–

  

<b>BioBall™ MaxiMotion™ PE-Inlay with Ceramic Head</b>						
HM35646	HM35648	HM35650	HM35652	HM35654	HM35656	HM35658
HM35660	HM35662	HM35664	HM35666	HM35668	–	–

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<b>BioBall™ MaxiMotion™ XPE Inlay with Ceramic Head</b>						
HM35669	HM35670	HM35671	HM35672	HM35673	HM35674	HM35675
HM35676	HM35677	HM35678	HM35679	HM35680	HM35681	HM35682
HM35683	HM35684	HM35685	HM35686	HM35687	HM35688	HM35689

<b>MaxiMotion™ PE-Inlay</b>						
HM35800	HM35801	HM35802	HM35803	HM35804	HM35805	HM35806
HM35807	HM35808	HM35809	HM35810	HM35811	—	—

<b>MaxiMotion™ XPE-Inlay</b>						
HM35812	HM35813	HM35814	HM35815	HM35816	HM35817	HM35818
HM35819	HM35820	HM35821	HM35822	HM35823	HM35824	HM35825
HM35826	HM35827	HM35828	HM35829	HM35830	HM35831	HM35832

<b>BioBall™ Adapter MST1</b>						
HM36002	HM36003	HM36004	HM36005	HM36006	—	—

<b>BioBall™ Adapter MST1 Offset</b>						
HM36022	HM36023	HM36024	HM36025	HM36026	—	—

<b>BioBall™ Adapter MSSY</b>						
HM37121	HM37122	HM37123	HM37124	—	—	—

<b>BioBall DELTA™ Ceramic Head</b>						
HM50028	HM50032	HM50036	HM50040	HM50044	HM50048	—

<b>Bipolar TwinSet™ Cup</b>						
HT00242	HT00243	HT00244	HT00245	HT00246	HT00247	HT00248
HT00249	HT00250	HT00251	HT00252	HT00253	HT00254	HT00255
HT00256	HT00257	HT00258	HT00259	HT00260	HT00262	—

– End of appendix –

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