

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
Primaro Cup

with specifications listed in the appendix

of the manufacturer:

OHST Medizintechnik AG
Grünauer Fenn 3
14712 Rathenow
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.

Effective date: 2021-01-20
Expiry date: 2024-03-27

Report No.: 13452PS08F
Process No.: PP – 13452
Certificate No.: 13452GB411210120A

Hamburg, 2021-01-20


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.

MEDCERT Identification Number: 0482

Form F10010009e EN / Rev. 7 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Design Examination Certificate

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Specifications

Primaro Cup (TPS)						
367-1190	367-1191	367-1192	367-1193	367-1194	367-1195	367-1196
367-1197	367-1198	367-1199	367-1200	367-1201	367-1202	—

Primaro Cup (TPS+BONIT®)						
367-1203	367-1204	367-1205	367-1206	367-1207	367-1208	367-1209
367-1210	367-1211	367-1212	367-1213	367-1214	367-1215	—

Primaro SF Cup (TPS)						
367-1216	367-1217	367-1218	367-1219	367-1220	367-1221	367-1222
367-1223	367-1224	367-1225	367-1226	367-1227	367-1228	—

Primaro SF Cup (TPS+BONIT®)						
367-1229	367-1230	367-1231	367-1232	367-1233	367-1234	367-1235
367-1236	367-1237	367-1238	367-1239	367-1240	367-1241	—

Primaro Cup (rough blasted)						
367-1534	367-1535	367-1536	367-1537	367-1538	367-1539	367-1540
367-1541	367-1542	367-1543	367-1544	367-1545	367-1546	—

PE Inlay Primaro Cup						
367-1252	367-1253	367-1254	367-1255	367-1256	367-1257	367-1258
367-1259	367-1260	367-1261	367-1262	367-1263	367-1264	367-1265
367-1266	367-1267	367-1268	367-1269	367-1270	367-1271	367-1272
367-1273	367-1274	367-1275	—	—	—	—

XL-PE Inlay Primaro Cup						
367-1276	367-1277	367-1278	367-1279	367-1280	367-1281	367-1282
367-1283	367-1284	367-1285	367-1286	367-1287	367-1288	367-1289
367-1290	367-1291	367-1292	367-1293	367-1294	367-1295	367-1296
367-1297	367-1298	367-1299	—	—	—	—

– End of appendix –

This appendix is integral part of the above-referenced certificate.
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