



## EC DESIGN-EXAMINATION CERTIFICATE

**475-00-00-DM**

*(in compliance with Annex II – point 4 of the Directive 93/42/EEC)*

### ITALCERT S.r.l.

certifies to the manufacturer

## **GO German Orthopedic Implants GmbH**

Barkhausenweg 10 22339 Hamburg - Germany

in the headquarters located in

Oststraße 4-10 – 22844 Norderstedt - Germany

that a design examination  
in compliance with the requirements of the  
Annex II – point 4 of the Directive 93/42/EEC  
has been conducted on  
the medical devices listed in the annex 1 of this certificate

and that  
the medical devices subjected to design examination  
conform to the essential requirements  
of the Annex I of the Directive 93/42/EEC

  
Dr. Ing. Roberto Cusolito  
MANAGING DIRECTOR

First Issue Date  
2020-04-30

Expire Date  
2024-05-26

This certificate must be published only in integral form and accompanied by its Annex 1  
This certificate is valid only in connection with valid certificate n° 474-00-00-DM  
This certificate is the English translation of the certificate n°475-00-00-DM issued by ITALCERT Srl in Italian language.  
In case of discrepancy you must refer to the original certificate issued in Italian language

## **Annex 1 to Certificate 475-00-00-DM**

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### **ACETABULAR SHELL SYSTEM *EasyHip Cementless Cups***

***Product codes:***

TF-00785 Declaration of Conformity – Version 3.0 dated 24/03/2020  
List of Articles - EasyHip Cementless Cups TF-00777, dated 12/2019

***Intended use and classification:***

Implantable medical device intended for use in hip arthroplasty (Class III)

***Documents subjected to design examination:***

TF-00773 Version 2.0 dated 24/03/2020

***Approval of the design examination:***

rif. DM589-20082-DM dated 2020-04-28

### **FEMORAL STEM SYSTEM *EasyHip Tapered Stems***

***Product codes:***

TF-00879 Declaration of Conformity – Version 1.0 dated 22/12/2019  
List of Articles TF-00871 - EasyHip Cemented Tapered Stem dated 12/2019  
List of Articles TF-00871 - EasyHip Cementless Tapered Stem dated 12/2019

***Intended use and classification:***

Implantable medical device intended for use in hip arthroplasty (Class III)

***Documents subjected to design examination:***

TF-00867 Ver.2.0 dated 20/03/2020

***Approval of the design examination:***

rif. DM589-20082-DM dated 2020-04-28

**Annex 1 to Certificate 475-00-00-DM**

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**FEMORAL STEM SYSTEM *EasyHip Cementless Conical Stems***

***Product codes:***

TF-00922 Declaration of Conformity – Version 1.0 dated 17/12/2019

List of Articles TF-00912 - EasyHip Cementless Conical Stem dated 12/2019

***Intended use and classification:***

Implantable medical device intended for use in hip arthroplasty (Class III)

***Documents subjected to design examination:***

TF-00907 Ver.3.0 dated 20/03/2020

***Approval of the design examination:***

rif. DM589-20082-DM dated 2020-04-28

Milan, 2020-04-30



Dr. Ing. Roberto Cusolito  
MANAGING DIRECTOR