

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60143483 0001

**Report No.:** 26300372 007

**Manufacturer:** DELPHOS IMPLANTS, Industria,  
Comercio, Importacao e Exportacao  
de Implantes Medicos, S.A.  
Estrada Manuel Correia Lopes Parque  
Empresarial Progresso, Armazem No. 5  
2785-126 Sao Domingos de Rana  
Portugal

**Products:** (see attachment for products included)

Replaces EC Certificate. Registration No. HD 60118184 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-10-09

**Date:** 2019-10-09

Notified Body



Rafal Byczkowski  
Zertifizierungsgestelle

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60143483 0001  
**Report No.:** 26300372 007

**Manufacturer:** DELPHOS IMPLANTS, Industria,  
Comercio, Importacao e Exportacao  
de Implantes Medicos, S.A.  
Estrada Manuel Correia Lopes Parque  
Empresarial Progresso, Armazem No. 5  
2785-126 Sao Domingos de Rana  
Portugal

**Product included:**

- Non-sterile plates for cranio-maxillofacial surgery
- Non-sterile screws for cranio-maxillofacial surgery
- Non-sterile plates for orthognathic and orthodontic surgery
- Non-sterile screws for orthognathic and orthodontic surgery

**Date:** 2020-03-04

**Notified Body**

  
**Rafal Byczkowski**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60143483 0001  
**Report No.:** 26300372 010

**Manufacturer:** DELPHOS IMPLANTS, Industria,  
Comercio, Importacao e Exportacao  
de Implantes Medicos, S.A.  
Estrada Manuel Correia Lopes Parque  
Empresarial Progresso, Armazem No. 5  
2785-126 Sao Domingos de Rana  
Portugal

**Products included:**

- Non-sterile bone plates for osteosynthesis for hand surgery
- Non-sterile bone plates for osteosynthesis for foot surgery
- Non-sterile bone screws for osteosynthesis for hand surgery
- Non-sterile bone screws for osteosynthesis for foot surgery
- Non-sterile bone wires

**Date: 2020-03-04**

**Notified Body**

  
**Rafal Byczkowski**

