



Health Technology Certification

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that  
the quality management system of

### Demophorius Limited

196 Archbishop Makarios III Avenue, Limassol 3030 Cyprus

Certificate No: 2288C02211203  
Original Approval: 02/12/2020  
References: W001 2288 03  
Issue Date: 16/12/2021  
Valid until: 24/05/2024

has been assessed by HTCert and found to comply with

### EN ISO 13485:2016

Scope of certificate:

- Design and Development, Production and Distribution of Sterile Absorbable Surgical Sutures.
- Production and Distribution of Blood collection tubes, Blood Transfusion Sets, Examination Gloves, Hypodermic Single Use Needles, Hypodermic Single Use Syringes, Infusion Sets, Sterile I.V. Cannulas, Surgical Gloves.
- Distribution of diagnostic equipment for haematology.

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director



*this certificate cancels and replaces 2288C02210502*



Health Technology Certification

# EC-CERTIFICATE

## DESIGN EXAMINATION

This is to certify that the  
quality management system of

**Demophorius Ltd**

196 Archbishop Makarios III Avenue, Limassol 3030 Cyprus

for design and manufacture of

Sterile Absorbable Surgical Sutures with or without needles

- PDO (Polydioxanone)
- PGA (Polyglycolic Acid)
- PGLA (Poly(Glycolide-co-L-lactide))

conforms to the provisions of the Council Directive 93/42/EEC.

The certificate is based on the result of the examination of the submitted design dossier according to Annex II, Section 4, of the Directive. Any changes which could affect conformity with the essential requirements of Directive 93/42/EEC, or with the conditions prescribed for use of the product must receive further approval from HTCert. For marketing of the products, a Full Quality Assurance System Certificate according to the requirements of Annex II, Section 3, of Council Directive 93/42/EEC is required.

**Certificate No:** 2288C03210501

**Issue Date:** 25/05/2021

**Original Approval:** 25/05/2021

**Valid until:** 26/05/2024

**References:** W002 2288 01

HTCert is a Notified Body according  
to Council Directive 93/42/EEC concerning medical  
devices with identification  
number 2803

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

**FILIPPOS KOTTIS**  
Certification Director

A blue ink signature of Filippos Kottis, written in a cursive style.



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### Demophorius Ltd

196 Archbishop Makarios III Avenue, Limassol 3030 Cyprus

for design and manufacture of

**Sterile Absorbable Surgical Sutures with or without needles**

- PDO (Polydioxanone)
- PGA (Polyglycolic Acid)
- PGLA (Poly(Glycolide-co-L-lactide))

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

**Certificate No:** 2288C04210501  
**Issue Date:** 25/05/2021  
**Original Approval:** 25/05/2021  
**Valid until:** 26/05/2024  
**References:** W001 2288 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director