DEMOPHORIUS

196 Archbishop Makarios III Av. Limassol 3030, Cyprus



Title of document: Declaration of Conformity

Manufacturer: Demophorius Limited

196 ARCHBISHOP MAKARIOS III AV.

LIMASSOL 3030, CYPRUS TEL: +357 25 749896 FAX: +357 25 749907

Medical Device:

DTEK non-absorbable with needles or without

needles.

Identification of a given number of devices: Please refer to mf-272 demophorius

identification product list v2.1 - NON- ABS

Classification: Class IIb (Implantable, Long-term surgically

invasive medical device as per Annex IX,

Section III Classification rule 8)

Conformity Assessment Route: Annex II (excluding section 4) of 93/42/EEC

A Statement that the identified devices meet the applicable provisions of the Directive:

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/ EEC for Medical Devices and applied standards (as per applied standards list included in the technical documentation). All relevant documentation is retained under the premises of the manufacturer. We hereby declare that Demophorius Limited is exclusively responsible for the declaration of conformity for the above mentioned devices.

Notified body name, address and identification number:

TÜV SÜD Product Service GmbH Certification Body • Ridlerstraße 65• 80339 Munich •

Germany

Identification number: CE 0123

EC certificate no: G1 048773 0038 Rev. 01

Expiry date: 06.11.2022

Identification of the person authorized to sign on Name: Theodosis Papas pyrou

behalf of the manufacturer:

Position: General Manager

Signature.

Version: 2.1 Date: 12/05/2020

info@demophorius.com