



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## DemeTECH Corp.

14175 NW 60th Ave  
Miami Lakes, FL, 33014  
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Absorbable and non-absorbable surgical sutures as listed in the annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

|                              |            |
|------------------------------|------------|
| Certificate registration no. | 291660 MR2 |
| Certificate unique ID        | 170612631  |
| Effective date               | 2016-03-05 |
| Expiry date                  | 2021-03-04 |
| Frankfurt am Main            | 2016-03-05 |

## DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.





**Annex to Certificate**  
**Certificate registration No.: 291660 MR2**  
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| <b>Device family</b>                 | <b>Device</b>  | <b>Class</b> |
|--------------------------------------|--|--------------|
| Non-absorbable Surgical Sutures      | DemeLENE – Polypropylene                                 | IIb          |
|                                      | DemeLENE – Polypropylene with Overstitch                 | IIb          |
|                                      | DemeBOND - Polyester (Braided)                           | IIb          |
|                                      | DemeSILK - Silk (Braided)                                | IIb          |
|                                      | DemeLON - Nylon (Monofilament)                           | IIb          |
|                                      | DemeDAC - Polyester (Braided without covering)           | IIb          |
|                                      | DemeLON Multi - Nylon Multifilament                      | IIb          |
|                                      | DemeSTEEL - Stainless Steel                              | IIb          |
| Sterile Synthetic Absorbable Sutures | DemeSORB – Polyglycolic Acid (PGA)                       | III          |
|                                      | DemeCRYL – Polyglactin 910 (PGLA)                        | III          |
|                                      | DemeQUICK – RAPID ABSORBABLE (PGR)                       | III          |
|                                      | DemeDIOX – POLYDIOXANONE (PDO)                           | III          |
|                                      | DemeDIOX (with OverStitch™ anchor) - POLYDIOXANONE (PDO) | III          |
|                                      | DemeCAPRONE – POLIGLECAPRONE (MO)                        | III          |