



DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

DemeTECH Corp.
5980 Miami Lakes Drive
Miami Lakes, FL, 33014
United States of America

Frankfurt a. M.,
2023-09-14

CONFIRMATION OF CERTIFICATION AND APPLICATION TO FULFILL THE REQUIREMENTS FOR REGULATION (EU) 2023/607

To whom it may concern,

DQS Medizinprodukte GmbH hereby confirms that the company:

***DemeTECH Corp.
5980 Miami Lakes Drive
Miami Lakes, FL, 33014
United States of America***

has implemented and maintains a Quality Assurance System that fulfils the requirements of MDD 93/42/EEC. Consequently, devices listed on the certificates with the registration number of 291660 MR2 and the unique ID 170772617 (issued on 2020-11-27 and valid until 2024-05-26), as well as registration number of 418998 MRA and the unique ID 170720806 (issued on 2018-08-26 and valid until 2023-08-25) can be placed on the market within the European Union bearing CE-0297 under the responsibility of DemeTECH Corp.

According to REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 Article 1, Article 120 of Regulation (EU) 2017/745 is amended as follows:

3. *By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.*

3a. *Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:*

- (a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;*
- (b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.*

3b. *Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.*

3c. *Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:*

- (a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;*
- (b) there are no significant changes in the design and intended purpose;*
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;*
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);*
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.*

The following items listed on the certificates are part of applications under Regulation (EU) 2017/745. The applications that were submitted and signed by DemeTECH Corp. are subject to approval by DQS Medizinprodukte GmbH:

Product name as stated by manufacturer	General product name	Risk class	Basic UDI-DI covered
DemeSORB	Absorbable Polyglycolic Acid Suture	Class III	1065292PGA0010073
DemeCRYL	Absorbable Polyglactin 910 Suture	Class III	1065292G0000100FF
DemeQUICK	Absorbable Polyglactin Rapid Suture	Class III	1065292PGR00100DY
DemeDIOX	Absorbable Polydioxanone Suture	Class III	1065292PX0001009L
DemeDIOX Barbed	Absorbable Polydioxanone Suture	Class III	1065292PXB00100GH
DemeCAPRONE	Absorbable Suture Polyglecaprone 25	Class III	1065292MO00010032
DemeLENE	Nonabsorbable Polypropylene Suture	Class IIb	1065292PM0001003R
DemeBOND	Nonabsorbable Polyester (Braided) Suture	Class IIb	1065292PB000100VT
DemeDAC	Nonabsorbable Polyester (Braided without covering) Suture	Class IIb	1065292PT0001007G
DemeSILK	Nonabsorbable Silk (Braided) Suture	Class IIb	1065292SK0001004G
DemeLON	Nonabsorbable Nylon (Monofilament) Suture	Class IIb	1065292NL00010022
DemeLON Multi	Nonabsorbable Nylon Multifilament Suture	Class IIb	1065292NM0001002K
DemeSTEEL	Nonabsorbable Stainless Steel Suture	Class IIb	1065292SW000100AU
DemeTECH PTFE	Nonabsorbable Polytetrafluoroethylene (PTFE) Suture	Class IIb	1065292TE000100ZS
DemeFORCE	Nonabsorbable Ultrahigh Molecular Weight Polyethylene Suture	Class IIb	1065292FR000100YD

Yours Sincerely,

DQS Medizinprodukte GmbH

David Heil

David Heil

Regulatory Affairs Manager

