Implants from Implantologists

SIC invent AG, Birmannsgasse 3, CH – 4055 Basel

Basel, 2024-05-03

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 in regard to the transitional provisions for certain medical devices, in particular with respect to the validity of the certificate issued under Council Directive 93/42/EEC on Medical Devices and the compliance of the devices specified therein and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Legal Manufacturer	**SIC invent AG** Birmannsgasse 3 4055 Basel Switzerland SRN: CH-MF-000015822
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt/Main Germany Ident. No. / Kenn-Nr.: *0297*
Directive Certificate	EC-Certificate Annex II – excluding Section 4 of Council Directive 93/42/EEC Certificate ID: 170771487
Original expiry date	2024-05-26
End date of extended validity	2028-12-31

We, **SIC invent AG,** as the manufacturer declare under our sole responsibility for the above listed Directive Certificate, the conditions for the legal extension of validity as required in Article 120(2) of Regulations (EU) 2017/745 are met and the devices listed below and specified in the Annex of the directive Certificate and we as their manufacturer are in compliance with the conditions listed in Article 120(3c) of Regulations (EU) 2017/745 for continued placing on the market and putting into service, namely by fulfilling the following conditions:

- The Directive Certificate as listed above covering the devices specified therein was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- The formal application to our notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us on March 7, 2024, for the devices listed in the Annex to the Directive Certificate and approved by our notified body on April 29, 2024.

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Gerichtsstand/Sitz: Basel

ZAZ Zollkonto: 9367-6
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EORI: DE5619769-0000

Bank: UBS AG, Basel
SWIFT/BIC: UBSWCHZH80A

IBAN CHF: CH94 0023 3233 1042 8801 Q
IBAN EUR: CH85 0023 3233 1042 8860 B
IBAN USD: CH20 0023 3233 1042 8861 E

- A signed written agreement in accordance with Section 4.3, second subparagraph of Annex VII MDR is in place.
- The **Quality Management System** in accordance with Article 10(9) MDR is in place and addresses all aspects mentioned therein.

The devices as listed in the Annex to the Directive Certificate

- continue to comply with the Directive 93/42/EEC.
- have no significant changes in the design and intended purpose.
- do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Schedule of Device:

Device name	MDD/ MDR Device classification	MDD Certificate Reference(s) of the devices and the NB Identification
Cylindrical, hybrid and conical Screw Implants	Class IIb	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297
Fixation Screws, Cover Screws	Class IIb	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297
Gingiva Shapers / Healing Abutments	Class IIb	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297
Prosthetic Abutments	Class IIb	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297
Bone Drills, Crestal Drills and Bone Taps	Class IIa	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297
Transfer Abutments, Impression Copings, Transfer Caps and Scan Adapters	Class I devices placed on the market in sterile condition	Certificate ID: 170771487 Certificate Registration No: 293238 MR2 Notified Body: 0297

Sincerely yours,

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