



– MANUFACTURER’S SELF-DECLARATION –

Manufacturer: Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, Minnesota 55110 USA

EU Authorized Representative: Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

Notified Body: BSI
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
The Netherlands

NB Number: 2797

EC Certificate CE 01777 Issued by BSI in accordance with Directive 93/42/EEC (MDD) on Medical Devices, Annex II excluding Section 4.

Product Description: BSI Certificate CE 01777 was first issued 1997-12-16 and expired 2022-12-15.
MammoSTAR Tissue Marker and Delivery Device

Indications for use: MammoSTAR Tissue Marker and Delivery Device is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Product Codes: STAR0801
STAR0802
STAR0831
STAR0832
STAR0833
STAR1001
STAR1031
STAR1032
STAR1033
STAR1101
STAR1102
STAR1121
STAR1401
STAR1402
STAR1403

Quality Management System Certificate (ISO 13485:2016): FM 38359



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To Whom It May Concern,

Whereas:

- (1) Carbon Medical Technologies, Inc. (CMT) is a medical device manufacturer located in the United States holding EC Certificate CE 01777 Issued by BSI (Notified Body Number 2797) in accordance with Directive 93/42/EEC (MDD) on Medical Devices, Annex II excluding Section 4.
- (2) BSI Certificate CE 01777 was first issued 1997-12-16 and has an expiry date of 2022-12-15.
- (3) CMT is currently undergoing certification under the superseding Regulation (EU) 2017/745 (MDR) for those same products covered by certificate CE 01777, listed within this declaration.
- (4) CMT continues to maintain compliance with the MDD and is committed to allowing the Notified Body to continue all appropriate MDD surveillance activities.
- (5) CMT certifies that there have been no significant changes in design or intended purpose to the devices subject to this self-declaration since the date of application of the MDR on May 25, 2021.
- (6) CMT conducts and maintains post-market surveillance, post-market clinical follow-up, vigilance, and market surveillance and has determined that there are no safety concerns for the devices subject to this self-declaration. Additionally, the Notified Body has not taken action on the certificate(s) subject to this self-declaration in the form of scope reductions or product suspensions, further evidencing the safety of the device(s) subject to this self-declaration.
- (7) CMT certifies that the Quality Management System is compliant with Article 10(9) of the MDR.
- (8) CMT has lodged an application with the Notified Body and has a signed written agreement in place for certification to the MDR.
- (9) MDR Amending Regulation EU 2023/607 indicates that certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until December 31, 2027.

Have Adopted the Position:

1. Legacy devices listed herein and covered by CE 01777 may continue to be made available on the market, provided CMT continues to meet the above requirements, until the issuance of the MDR certificate or December 31, 2027, whichever is first.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Jared Klein", is written over a horizontal line.

Jared Klein
Regulatory Affairs Specialist
Carbon Medical Technologies, Inc.

April 20, 2023

Date: