

Monday, January 16, 2023

To Whom It May Concern,

Whereas:


- (1) Carbon Medical Technologies, Inc. (CMT) is a medical device manufacturer, manufacturing MammoSTAR™ Biopsy Site Identifier, 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.
- (4) CMT has engaged the services of Donawa Lifescience as its Authorized Representative [EC REP] for these devices within the EEA (European Economic Area)
- (5) CMT has engaged with various Importers within the EEA to place devices on the market and make them available for sale.
- (6) EU MDR Article 120 paragraph 2 states that Certificates issued by notified bodies in accordance with MDD from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, or until 27 May 2024.
- (7) EU MDR Article 120 Paragraph 4 states that devices lawfully placed on the market pursuant to Directive 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 ('legacy devices'), may continue to be made available on the market or put into service until 27 May 2025.
- (8) In the event that a Certificate has not been issued for these devices under the MDR by the expiry date of BSI certificate number CE 01777, the Manufacture and Authorized Representative, in regard to distribution and sale of such 'legacy' devices,

HAVE ADOPTED THIS POSITION:

1. Any legacy device covered by CE 01777 that is sold by CMT and imported into the EEA prior to 15 DEC 2022 been 'placed on the market' by the Importer.
2. Devices referred to in paragraph 1 can continue to be made available on the EEA market and sold (whether importer -to-distributor, distributor to-distributor, or distributor-to-end user) until 27 May 2025.

Mammotome sells the following MammoSTAR™ products codes which fulfill the above content:
STAR0831, STAR0832, STAR0833, STAR1031, STAR1032, STAR1033, STAR1001, STAR1401, STAR1402,
STAR1403, STAR0801, STAR0802, STAR1101, STAR1102, STAR1121

Yours sincerely,


John Cummings
Director, Quality & Regulatory Affairs
On behalf of Devicor Medical Products, Inc. d.b.a Mammotome

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