



– DECLARATION OF CONFORMITY –

Manufacturer Carbon Medical Technologies, Inc.
Address 1290 Hammond Road
Saint Paul, MN 55110, USA
European Representative Donawa Lifescience Consulting
Piazza Albania, 10
00153 Rome, Italy
Product: BiomarC® Tissue Marker
Product Codes: 040113, 040114, 040116, 040117, 040118, 040125, 040203, 040204, 040213, 040214, 040219, 040220, 040221, 040222, 040223, 040226, 040227, 040228, 040239, 040300, 040306, 040307, 040308, 040309, 040310, 040317, 040318, STAR0801, STAR0802, STAR0831, STAR0832, STAR0833, STAR1031, STAR1032, STAR1033, STAR1101, STAR1102, STAR1121, STAR1401, STAR1402 & STAR1403
GMDN Code: 40808 (Marker, lesion localization, implantable)
Classification (MDD, Annex IX): IIb, Rule 8
Classification (TGR, Schedule 2): 11b, 3.4 Rule 2

We hereby declare, under our sole responsibility, that the above products meet the provisions of the following EC Council Directives, Australian Therapeutic Goods Regulations, and voluntary harmonized standards. All supporting documentation is retained at the manufacturer and/or the authorized European Representative offices.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended by Directive 2007/47/EC.

Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods Regulations 2002.

Standards:

Harmonized standards (published in the Official Journal of the European Communities) applicable to these products are listed in the Technical File, the product specifications, and the Design History File.

Notified Body:

BSI
Davy Avenue
Milton Keynes MK5 8PP

Full Quality Assurance Certificate:

CE01777

Quality Management System Certificate:

FM38359

Signature/Date:

Name:

Title:


Andrew Adams

8/6/13

Director – Regulatory Affairs & Quality Assurance

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Declaration Revision History:

3/04	Initial declaration for 040106, 040105
1/06	Added 040203 and 040204 per S1
4/06	Modified to declare for Australia. Deleted 040106, and 040105 which not marketed.
6/07	Modified to add 040300, 040113, per S2
6/08	Updated European Representative's address and added 040114, 040213, 040214, 040219, 040220, 040221, 040222, 040223, 040226, 040306, 040307, 040308, and 040309 per S4
3/10	Updated European Representative's name and added 040116 per S6
3/10	Added "as amended by Directive 2007/47/EC" to general applicable directives per S7
7/10	Added 040227 and 040228 per S8 and revised 6/08 revision history reference to S4
8/10	Added 040117 and 040310 per S9
9/10	Added 040118 per S10
8/11	Added 040239 and 040318 per S11
10/11	Added 040317 per S12 and corrected 8/11 revision history product code from 040329 to 040239
1/12	Added 040525, 040526, and 040527 per S13
8/12	Added 040530 per S14
10/12	Added STAR0801, STAR1101, STAR1121, & STAR1401 per S15
11/12	Added STAR0831 & STAR1031 per S16
3/13	Added STAR0802, STAR0832, STAR1032, STAR1102, & STAR1402 per S17
4/13	Added 040125 and removed 040525, 040526, 040527 & 040530 per S18
6/13	Added STAR0833 & STAR1033 per S19
8/13	Added STAR1403 per S20