Declaration of Conformity

Biocompatibles

Biocompatibles UK Ltd,
Chapman House,
Farnham Business Park,
Weydon Lane,
Farnham,
Surrey, GU9 8QL.
UK

DC BEAD®

Product Code	Calibrated Size		Product Code	Calibrated Size
DC1V001	70-150µm		DC2V001	70-150µm
DC1V103	100-300µm		DC2V103	100-300µm
DC1V305	300-500µm		DC2V305	300-500µm
DC1V507	500-700µm		DC2V507	500-700µm
DC1V709	700-900µm		DC2V709	700-900µm

This declaration of conformity is issued under the responsibility of the manufacturer, Biocompatibles UK Ltd.

Product classification: **Class IIb**.

The undersigned, hereby declares that the medical devices specified above comply with the Medical Device Directive 93/42/EEC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed onto the market)

This declaration is supported by: EC Full Quality Assurance Certificate number CE 79333, issued to Biocompatibles UK Ltd by the BRITISH STANDARDS INSTITUTION (Notified Body Number 0086) according to Annex II of the Medical Device Directive 93/42/EEC, demonstrating compliance to ISO 13485.

A list of standards adhered to is referenced below.

Signed:---------- Date: 09 Oct 2013

Dr. Alistair Taylor
Director of Regulatory Affairs

DC Bead

Essential Principles and Evidence of Conformity

REFERENCE: **Essential Requirements per Annex I MDD 93/42/EEC for DC Bead.**

The following standards were applied throughout the design and development of DC Bead.
Some standards have now been updated** or withdrawn and replaced¥,
in which case the most current version of the standard or its replacements is also listed.

Standard	Standard Name	Date	Committee
93/42/EEC 2007/47/EC	Medical Device Directive Revision to Medical Device Directive	1993 March 2010	European Commission
ISO9001:2000** ISO9001:2008	Quality Management systems – Requirements	December 2000 November 2008	QS/1
BS EN ISO 13485:2001** ISO 13485:2003** ISO 13485:2012	Quality systems. Medical devices. Particular requirements for the application of EN ISO 9001 Medical devices: Quality management systems. Requirements for regulatory purposes	March 2001 July 2003 March 2012	CH/210/1
BS EN ISO 14971:2001** BS EN ISO 14971 :2012	Medical devices – Application of risk management to medical devices	March 2001 July 2012	CH/210/4
BS EN 540:1993¥ BS EN ISO 14155-1:2003** BS EN ISO 14155:2011	Clinical investigation of medical devices for human subjects Clinical Investigations of medical devices for human subjects – general requirements	August 1993 March 2003 February 2011	CH/194 CH/194/-/1
BS EN ISO 14630:1998** BS EN ISO 14630:2008** BS EN ISO 14630 :2012	General requirements for non-active surgical implants Non active surgical implants. General requirements	January 1998 November 2009 December 2012	CH/150
BS EN ISO 10993-1:2003** ISO 10993-1:Oct 2009	Biological evaluation of medical devices – Evaluation and testing Biological evaluation of medical devices. Evaluation and testing within a risk management process	October 2003 June 2010	CH/194
ANSI/AAMI ISO 11134:1994¥ BS EN 554:1994¥ BS EN ISO 17665-1:2006 BS EN 17665-2:2009	Sterilization of health care products-Requirements for validation and routine control-Industrial moist heat sterilization, 2ed Sterilization of medical devices. Validation and routine control of sterilization by moist heat Sterilization of healthcare products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices Sterilization of healthcare products. Moist heat guidance on the application of ISO 17665-1	February 1994 Oct 1994 September 2006 February 2009	ISO/TC 198 CH/198 CH/198 CH/198
BS EN 556-1:2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally-sterilized medical devices.	December 2001	CH/198
BS EN ISO 14644-1:1999	Cleanrooms and associated controlled environments. Classification of air cleanliness	August 1999	LBI/30
BS EN ISO 14644-2:2000	Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	December 2000	LBI/30
BS EN 868-1:1997¥ BS EN ISO 11607-1:2009 BS EN ISO 11607-2:2006	Packaging materials and systems for medical devices which are to be sterilized. General requirements and test methods. Packaging for terminally sterilized medical devices Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	December 1997 February 2010 May 2006	LBI/35 TC/198 LBI/35 LBI/35
BS EN 1041:1998** BS EN 1041:2008	Information supplied by manufacturers with medical devices	July 1998 August 2008	CH/210/3
BS EN 980:2003** BS EN 980:2008¥ BS EN ISO 15223-1:2012	Graphical symbols for use in the labelling of medical devices Symbols for medical device labelling Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements	August 2003 June 2008 July 2012	CH/210/3

DC Bead
Product Codes and Intended Use

Size Range	Intended Use
Product Code / **Product Code** / **Calibrated Size** DC1V001 / DC2V001 / 70-150µm DC1V103 / DC2V103 / 100-300µm DC1V305 / DC2V305 / 300-500µm DC1V507 / DC2V507 / 500-700µm DC1V709 / DC2V709 / 700-900µm	DC Bead is primarily intended as an embolic agent to treat vessels supplying malignant hypervascular tumours. DC Bead is compatible with doxorubicin, which can be loaded prior to embolisation and then, as a secondary action, elute a local, controlled and sustained dose to the tumour after embolisation.
Product Code / **Product Code** / **Calibrated Size** DC1V001 / DC2V001 / 70-150µm DC1V103 / DC2V103 / 100-300µm DC1V305 / DC2V305 / 300-500µm DC1V507 / DC2V507 / 500-700µm	DC Bead is primarily intended as an embolic agent to treat vessels supplying malignant colorectal cancer metastasised to the liver (mCRC). DC Bead is compatible with irinotecan, which can be loaded prior to embolisation and then, as a secondary action, elute a local, controlled and sustained dose to the mCRC after embolisation.