



EC DECLARATION OF CONFORMITY

according to annex III of the Council Directive 98/79/EEC concerning in vitro diagnostic medical devices

We: SMART BIOTECH LTD, 2 Bergman St, Science Park Rehovot 76705, Israel
(PHONE: 972-8-9470240; FAX: 972-8-9469608)

declare under our sole responsibility that the products:

SMARTube™ HIV&HCV
SMARTube™ HIV
SMARTube™ HCV
SMARTube™

meet the provisions of the Council Directive 98/79/EEC concerning in vitro diagnostic medical devices which apply to them, manufactured throughout the validity of the current revision of the Technical Dossier.

The products are intended to be used for collection of blood samples as a "specimen receptacle" for enhancement of antibodies, therefore are not covered by Annex II of the IV Diagnostic Medical Device Directive.

Conformity assessment was performed according to Annex III of the Directive.

The following standards were used to prove the products' conformity with the essential requirements of the above Directive:

- **ISO13485:2003** – Quality Systems-Medical Devices-System requirements for regulatory purposes
- **ISO 14971:2007** – Medical devices-Application of risk management to medical devices
- **ISO 13408-1:2008** – Aseptic processing of healthcare products – General requirements
- **ISO 14644-1:1999** – Clean rooms and associated controlled environments – Classification of air cleanliness
- **EN 980:2003** – Graphical symbols for use in the labeling of medical devices;
- **EN 1041:2008** – Information supplied by the manufacturer with medical devices;
- **EN 13640:2002** – Stability testing of in vitro diagnostic reagents

The authorized representative within the EU who has been empowered to enter into commitments on our behalf is:

MedNet GmbH, Borkstrasse 10, 48163 Muenster, Germany Phone +49 251 322660, Fax +49 251 3226622,
(Name, address, phone and fax numbers)

Date: 12.7.09


Dr. Tamar Judah-Cohen - CTO
