




EC Declaration of Conformity to Medical Devices Directive 93/42/EEC
Manufacturer: Allmed Medical GmbH

Family name	Bicarbonate Containers
Device name	BioCarb Cartridge, BioCard Bag
Mode of contact	Non-invasive
Duration of contact	Short term
CLASS	IIb
RULE	3
Code Bicarbonate Cartridge	BioCarb B; BioCarb G

Declaration of Conformity

Allmed Medical GmbH, Karl-Marx-Str.23 01109 Dresden-Germany, declares that **Bicarbonate Cartridge** conforms to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and is in accordance with **Annex II** Conformity Assessment Procedure and EN ISO 13485 registered Quality Management System as implemented by European Communities (Medical Devices) Regulations into the Allmed Medical GmbH QMS, as verified by EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH; Quarat Center, Wittichstrasse 2, 64295 Darmstadt-Germany( 0535).



Allmed Medical GmbH confirms that no other application has been lodged with another Notified Body for the same product-related Quality Management System.

Allmed Medical GmbH undertakes to develop, implement and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Allmed Medical GmbH undertakes to develop, implement and maintain a documented post-production experience monitoring programmed, along with notification of incidents notifiable under the European Medical Device Vigilance system guidelines.

Allmed Medical GmbH confirms that no medicinal products/drugs are incorporated in any devices covered by the Product Schedule.

Allmed Medical GmbH undertakes to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Managing Director	Juergen Haaser, PH.D.	 	01/09/2009	Eu.Dec.011
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