Allmed **EC Declaration of Conformity to Medical Devices Directive 93/42/EEC**

Manufacturer: Allmed Medical GmbH

Family name		Bicarbonate Containers
Device name		Bicarbonate Cartridge, Bicarbonate Bag
Mode of contact		Non-invasive
Mode of duration		Short term
CLASS		IIb
RULE		3
Certificate No.		CE 574474
Code	**Bicarbonate Cartridge**	**BioCarb B**
		BioCarb G 650, 720, 740, and 750 gm.
		BioCarb Q 650, 720, 740, and 750 gm.
	Bicarbonate Bag	**DiaCard** 650, and 900 gm.
		DiaCard S 650, and 900 gm.

Declaration of Conformity

Allmed Medical GmbH, Mittelbacherstr.18 01896, Pulsnitz, Germany, declares that **Bicarbonate Cartridge, and Bicarbonate Bag** conforms on our own responsibility to the relevant provisions of the EC Council Directive 93/42/EEC as amended by 2007/47/EEC and is in accordance with Annex II.3 Conformity Assessment, as *verified by* **BSI Healthcare (Notified Body 0086),** *Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP, United Kingdom*

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 Quality plan to ensure continued adequacy and efficacy.*

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

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 according to the OBL agreement.*

Allmed Medical GmbH *undertakes to inform the appointed Notified Body of any planned or unplanned significant change to the Product Schedule, including significant design change to devices according to the OBL agreement.*

This declaration is valid up to 23.03.2022

Managing Director **Dr. Jürgen A. Haaser**		**20.04.2017**	**Eu.Dec.003** **09**