

| | | |
|-------------------------|------------------------------|---|
| 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.

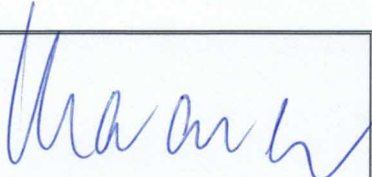
Allmed Medical GmbH undertakes to develop, implement and maintain a documented post-production experience monitoring programme, along with notification of incidents notifiable under the European Medical Device Vigilance system guidelines and OBL agreement.

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 |