axcom
Battery Technology

EG – DECLARATION OF CONFIRMITY

We, the Axcom GmbH
Carl-Friedrich-Benz-Str. 15
47877 Willich
Name and address of the manufacturer or of the distributor established in the EU

declare in sole responsibility, in accordance with

Annex VII of Council Directive 93/42 / EEC of 14 July 1993, transposed by the Medical Devices Act (MPG) of 07 August 2002

that this medical device (class I)

NIMH Battery MB1072*

Type designation and article number

* Replacement accumulator suitable for use in the following medical - technical devices:
NiMH battery suitable for Carefusion Alaris Asena syringe pump GH/CC/PK

to which the declaration relates, complies with the essential requirements of annex I to that EC directive and of the following standard(s) or normative document(s), as far as they apply:

EN 60601-1 : 2006 / DIN VDE 0750 Part1 / 2007
DIN EN 414 / Attachment A

Title and / or number (possibly date of issue) of the standard or other normative documents

This declaration is based on an assessment that this product is a medical-technical accessory and a medical device of class I according to regulation 12 appendix IX as well as a technical documentation required by the Medical Devices Act (MPG) for this medical device / or number (possibly date of issue) of the standard or other normative documents.

Marzena Schwarz-Szymura Axcom GmbH, Carl-Friedrich-Benz-Str. 15, D-47877 Willich
Name / address of the legally responsible person

Willich, 07/11/19
Place / date of the exhibition

Signature of the authorized person

This EC declaration of conformity lapses if the replacement battery specified above is modified, relabelled or altered without the consent of Axcom GmbH

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