

EU DECLARATION OF CONFORMITY

Certificate Number: ZP 06-014 Flow-metering device_09-04

Manufacturers Name: GCE, s.r.o.

Manufacturers Address: Žižkova 381, 583 01 Chotěboř, Czech Republic

SRN (Single Registration Number): 003172 RZPRO

Product Group: Flow-metering device

Name of the Device (s): MEDIFLOW II

Product code: 7552

Risk Classification: IIa

GMDN code: 61366

Other used standards: EN ISO 15002:2008

Notified Body name: DNV Product Assurance AS

Notified Body Address: Veritasveien 3, N-1363 Høvik, Norway

Notified Body Identification number: 2460

EC Certificate Number: 10401-2017-CE-CZS-NA-PS

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that the medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature: _____ Place and date (dd.mm.yyyy) of issue: _____

..... Chotěboř

Tereza Šnapková

Regulatory Specialist, On behalf of Tomáš Janeček, managing director.

Note: List of variants is in attachment of this document.