DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC - 2007/47EC Amending

Manufacturer:

GCE s.r.o.
Žižkova 381
583 81 Chotěboř
CZECH REPUBLIC

The GCE s.r.o. herewith declares under his sole responsibility that the product

Product name:	Suction Equipment
Model:	MEDIEVAC + MEDIEJECT
Risk Classification:	IIa

is in conformity with applicable regulation

Directive:	MDD 93/42/EC, Annex II – 2007/47EC Amending
Quality Assurance Standards:	EN ISO 9001:2008 EN ISO 13485:2012
Procedural Standards:	EN ISO 10079-3:2014 EN 980:2008 EN ISO 14971:2012 EN 1041:2008 + A1:2013 EN 1789:2007 + A1:2010 + A2:2014

Product is in compliance with the requirements of Annex II the MDD 93/42/EEC and is safe for to be declared using in standard conditions.
Any modification to the product, not authorized by us, will invalidate this declaration.

EC Certificate No. 73547-2010-CE-CZS-NA 6.0 issued by Det Norska Veritas, Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434.

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Place of Issue: Chotěboř

Signature: Jana Jelínková
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