



# EC Declaration of conformity

Manufacturer:	MEDORO s.r.o., Hraniční 10, 530 03 Pardubice, IČ: 26002612
Product:	Dicompass
Purpose:	DICOM data viewing and processing, image data acquiring and storing to DICOM format
Classification:	I Ib

This product is in compliance with DIR 93/42/EEC about medical devices is safe with purpose of usage under usual conditions. The manufacturer took measures for assuring compliance with technical documentation and basic law requirements.

This statement is issued by manufacturer on the basis of proving compliance with the system of quality according following laws, government orders and standards:

22/1997 Sb.	MEDDEV 2.1/6
123/2000 Sb.	DIR 93/42/EEC
316/2000 Sb.	DIR 2007/47 ES
336/2004 Sb.	ČSN EN ISO 13485:2003
350/2011 Sb.	ČSN EN ISO 14971:2012
378/2007 Sb.	ČSN EN ISO 1041:2008
501/2000 Sb.	

Certificate no:	13 0723 QS/NB
Issue date:	19.8.2013
Validity date:	13.8.2018
Notified body 1023:	INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s., třída Tomáše Bati 299, Louky, 763 02 Zlín, Česká republika, IČ: 47910381

