

EC DECLARATION OF CONFORMITY

1. Name and address of Supplier:	Digiterm Ltd., Ipar út 7., H-3200 Gyöngyös, Hungary		
2. Subject of Declaration / Product:	Description:	Therapy chair	
	Model:	Comfort-4 Eco	723C4E00
		Comfort-4 Battery	723C4B00
		Comfort-4 Plus	723C4P00

3. The manufacturer herewith declares that the above mentioned products meet the provisions of following Directives:

93/42/EEC (14 June 1993) Concerning medical devices
Amended by:
98/79/EC (27 October 1998)
2000/70/EC (16 November 2000)
2001/104/EC (7 December 2001)
1882/2003/EC (29 September 2003)
2007/47/EC (5 September 2007)
2011/65/EU (8 June 2011) on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

As well as the requirements of under mentioned harmonized Standards:

EN 980:2008 (EN ISO 15223-1:2012)
EN 1041:2008
EN ISO 10993-1:2009+AC:2010
EN ISO 10993-5:2009
EN ISO 13485:2016
EN ISO 14971:2012
EN 60601-1:2006+AC:2010+A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2007
EN 60601-2-52:2010
EN 62366:2008
EN 50581:2012

4. Complementary information

Classification: Class I, Rule 12 according to Annex IX of the Medical Device Directives 93/42/EEC (14 June 1993)

Quality System: ISO 9001:2015, EN ISO 13485:2016
CE Certiso Kft., Gyár u. 2., H-2040 Budaörs

Note: This statement of conformity is valid in connection with the release document for the respective batch of produced devices.



The form of Declaration of Conformity meets the requirements of EN ISO/IEC 17050-1:2004 Standard

29 October 2019
Gyöngyös, Hungary



István Hegedűs
Managing Director

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