

## 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	Article Nr.:	723C3E00
Model:	Comfort-3 Eco	Article Nr.:	723C3F00
	Comfort-3 Flex		

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

DIGITERM LTD.  
IPAR UT 7., GYONGYOS  
H-3200 HUNGARY  
4.

02 September 2019  
Gyöngyös, Hungary

István Hegedűs  
Managing Director