

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.



DIGITERM LTD.
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4.

02 September 2019
Gyöngyös, Hungary

István Hegedűs
Managing Director