EU Declaration of Conformity

Draft in accordance with Regulation (EU) 2017/745

Author:	Sruthi Subbaraman
Version:	February 5, 2024anuary 11, 2024
Data classification:	**Classified**

EU Declaration of Conformity

Regulation (EU) 2017/745

The draft EU Declaration of Conformity is provided as per Article 19 and Annex IV of the EU MDR 2017/745:

Name of the Manufacturer:	Tired of Cancer B.V.
Address of the Manufacturer:	Homeruslaan 79, 3581ME Utrecht, The Netherlands
Single Registration Number of the Manufacturer:	NL-MF-000000800
Trade Name of the Device(s):	Untire Now
Device Version	1.0
Device Item Number(s):	Android - https://play.google.com/store/apps/details?id=com.tiredofcancerapp.untirenxt.basic Apple - https://apps.apple.com/us/app/untire-now/id1661118356
Intended Purpose	The Untire Now application is an unguided tool intended for use by cancer patients and survivors to help them to reduce their cancer-related fatigue and to improve their quality of life.
Basic-UDI:	1163357UntireNowR3
Current UDI-DI:	N/A
EMDN Code:	Z11010492
Risk Classification:	Class I, Rule 11, According to Annex VIII of the Regulation (EU) 2017/745
List of Harmonized Standards:	• EN ISO 13485: 2016 Medical Devices – Quality management systems – Requirements for regulatory purposes. • EN ISO 14971: 2019 Medical Devices – Application of risk management to medical devices.

	• EN ISO 15223-1: 2016 Medical devices – Symbols to be used with medical device labels, labelling, information to be supplied – Part 1: General requirements. • EN 62304: 2006 Medical device software – Software lifecycle processes. • EN 62366: 2008 Medical devices – Application of usability engineering to medical devices. • EN IEC 82304-1: 2016 Health software — Part 1: General requirements for product safety
Conformity Assessment Procedure:	Article 52 (7) - Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: "Tired of Cancer B.V." We, hereby, declare that the medical device mentioned above meets the provisions and is in conformance with the REGULATION (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality Management System in compliance with EN ISO 13485: 2017, and ISO 27001: 2013. All supporting documents is retained at the premises of the legal manufacturer.

Object of declaration: The software "Untire Now" application is an unguided tool intended for use by cancer patients and survivors to help them to reduce their cancer-related fatigue and to improve their quality of life. The app can be retrieved from the Google PlayStore for Android and the Apple AppStore for iOS. The software can be found with the following icon:

Figure 1 Logo of Untire Now App

Signed by –

Name: Dr. Bram Kuiper

Function: CEO/Founder

Signature:

Date:
Place of signing: Tired of Cancer B.V., Koningin Wilhelminalaan 5, 3527LA, Utrecht, The Netherlands

The following information is provided in the EU Declaration of Conformity:

- Registered trade name of the legal manufacturer, contact, and address.
- A statement that the EU Declaration of Conformity is issued under the sole responsibility of the legal manufacturer.
- Basic UDI
- EMDN code
- Product and trade name, product code, or other reference allowing identification and traceability.
- Intended purpose.
- Risk class of the Untire Now app in accordance with Annex VIII.
- List of harmonized standards.
- A statement that the Untire Now app is covered in conformance with the EU MDR 2017/745.

Document control

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Reviewed by:	**Atse Aukes**	Chief Growth Officer, Tired of Cancer BV
Approved by:	**Dr. Bram Kuiper**	CEO/ Founder, Tired of Cancer BV
Version:	January 11, 2024	
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