Tired of Cancer

EU Declaration of Conformity

Draft in accordance with Regulation (EU) 2017/745

Author:	Sruthi Subbaraman
Version:	January 22, 2025
Data classification:	**Internal use only**

untire

An app that helps with cancer fatigue

EU Declaration of Conformity

Regulation (EU) 2017/745

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

Name of the Manufacturer:	Tired of Cancer B.V.
Address of the Manufacturer:	Koningin Wilhelminalaan 5, 3527LA, Utrecht, The Netherlands
Single Registration Number of the Manufacturer:	NL-MF-000000800
Trade Name of the Device(s):	Untire App
Device Version:	4.0
Device Item Number(s):	Google PlayStore – https://play.google.com/store/apps/details?id=com.tiredofcancerapp.untirenxt.classic Apple AppStore –https://apps.apple.com/app/Untire/id6670487914
Intended Purpose:	The software 'Untire' is a mobile application that helps manage fatigue in patients with cancer and cancer survivors and furthermore helps to improve their quality of life.
Basic-UDI:	87202992180UntireFU
Current UDI-DI:	08720299218024
EMDN Code:	Z110603
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: 2021 Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements. • EN 62304: 2006 Medical device software – Software life-cycle processes. • EN 62366: 2008 Medical Devices – Application of usability engineering to medical devices.
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". 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: 2016, ISO 27001: 2013. All supporting documents is retained at the premises of the legal manufacturer.

Object of declaration: The software "Untire" is a mobile application that helps reduce fatigue in patients with cancer or cancer survivors, and furthermore, helps to improve their quality of life. The app can be retrieved from the Google PlayStore for Android and the Apple store for iOS. The software can be found with the following icon:

Figure 1 Logo of Untire App

Signed for and on behalf of –

Name: Dr. Bram Kuiper

Function: CEO/Founder

Signature:

Date: 22/01/2025

Place: Tired of cancer B.V., Koningin Wilhelminalaan 5, 3527 LA, 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
- UDI-DI
- EMDN code
- Product and trade name, product code, or other reference allowing identification and traceability.
- Intended purpose.
- Risk class of the Untire app in accordance with Annex VIII.
- List of harmonized standards.
- A statement that the Untire app is covered in conformance with the EU MDR 2017/745.

Document control

Author(s): BV	**Sruthi Subbaraman**	Head of Legal & Regulatory Affairs, Tired of Cancer
Reviewed by:	**Atse Aukes**	Chief Growth Officer, Tired of Cancer BV
Approved by:	**Dr. Bram Kuiper**	CEO/Founder, Tired of Cancer BV
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Tired of Cancer BV
Koningin Wilhelminalaan 5
3527LA Utrecht
The Netherlands

+31 (0) 85 018 76 08
info@tiredofcancerapp.com
www.tiredofcancerapp.com

CC NL: 59422610
IBAN NL 44 TRIO 0197 7937 89
VAT 853475349 B 01