

1 **EU TYPE EXAMINATION CERTIFICATE**  
2 **Radio Equipment Directive 2014/53/EU – Annex III**

3 EU Type Examination Certificate No.: **ENW25RED0005**  
4 Equipment: **MightySat**  
5 Manufacturer: **Masimo Corporation**  
6 Address: **52 Discovery  
Irvine, CA 92618 USA**

7 This equipment and any acceptable variation thereto is specified in the schedule to this certificate and the documents therein referred to.

8 Element Materials Technology Portland-Evergreen, Inc. (hereafter referred to as Element Materials Technology) Notified Body number 0981 in accordance with Article 26 of the Council Directive 2014/53/EU of 16 April 2014, certifies that this equipment has been found to comply with the Essential Requirements relating to the design and construction of radio equipment given in the following Articles of the Directive:

**3.2 – Radio spectrum,**

**The manufacturer is responsible for additional assessment to all other applicable articles.**

The examination and test results are recorded in the confidential report MASIO0940.2 Rev 2.

9 Compliance with the Essential Requirements, with the exception of those listed in section 19 of the schedule to this certificate, has been assured by compliance with:

**EN 300 328 V2.2.2:2019-07**

10 This EU-Type Examination certificate relates only to the design and construction of the specified equipment in accordance with Directive 2014/53/EU. Further requirements of this Directive apply to the manufacture and supply of this equipment. These are not covered by this certificate.

11 This certificate and its schedules may only be reproduced in its entirety and without change. This certificate is issued in accordance with the rules of the Element Materials Technology Radio Certification Scheme and remains valid for only so long as the equipment conforms to the type described herein.

12 Any deviation to the design and construction of the specified equipment that is not certified by Element Materials Technology shall render this certificate invalid.



Brian Fahey, Certification Engineer  
Signed for and on behalf of Element

Issue date: 2025-04-21

CSF301-US 11.0 Page 1 of 5

13 **SCHEDULE TO EU TYPE EXAMINATION CERTIFICATE**

14 **ENW25RED0005**

15 **General description of equipment or protective system included within the scope of this certificate**

The talon is a standalone fingertip pulse oximeter that combine the functionality of an instrument, sensor, and technology board into a single portable instrument that fits on user's finger. The device will be capable of calculating functional oxygen saturation (SpO<sub>2</sub>), pulse rate(PR), perfusion index(Pi), Pleth respiration rate(RRp), Respiratory Effort index(REi), waveforms, and output this information via display screen or wirelessly over Bluetooth link. The Talon will be powered by 2 disposable AAA batteries and be used as a spot-check instrument, and as such will not contain alarm functionality.

The MightySat Fingertip Pulse Oximeter is indicated for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin(SpO<sub>2</sub>), Pule Rate(PR), Perfusion index(PI), Pleth Respiration rate(RRp), and Respiration Effort Index(REi).

The MightySat Fingertip Pulse Oximeter is intended for spot-checking on people >30kg(66lbs) during no motion and motion condition, and for people who are well or poorly perfused. This device is suitable for use in hospitals, hospital-type facilities, Mobile, and home environments.

16 **Technical description**

Frequency bands:	2402 – 2480 MHz
Transmit power / power range:	2 mW
Channel spacing:	2 MHz
Duty cycle:	100%
Type of modulation:	GFSK
Type of antenna and gain:	PCB Trace, 0.79 dBi
Hardware version:	N/A
Software version:	V2000-002; Build-001

17 **Technical Documents describing the certified equipment**

The list of technical documents is given in Appendix A to this schedule.

18 **Test report No. (associated with this certificate issue):** MASIO0940.2 Rev 2

19 **Essential Requirements (Directive Article 3)**

Covered by application of the standards listed in section 9 of this certificate and the assessment conducted in the test report/s listed in section 8 of this certificate.

20 **“Restrictions on Use”, if any:**

None.

21 **“Routine tests”, if any:**

None.

**SCHEDULE TO EU TYPE EXAMINATION CERTIFICATE  
ENW25RED0005**

**Other information, if any:**

22

None.

**Photographs**

23



**24 Details of markings**



**25 Details of variations to this certificate**

None

**SCHEDULE TO EU TYPE EXAMINATION CERTIFICATE**  
**ENW25RED0005**

**Notes to CE marking**

26

In respect of CE Marking, Element Materials Technology accepts no responsibility for the compliance of the equipment against all applicable Directives in all applications.

27 **Notes to this certificate**

Element Materials Technology certification reference: Project number TS-MASI-0089.

Throughout this certificate, the date format yyyy-mm-dd (year-month-day) is used.

Notified Body 0981 is the designation for Element Materials Technology, Portland-Evergreen Inc.

28 **Conditions for the validity of this certificate**

This certificate remains valid for **18 months after the date of issue** so long as:

- (i) The equipment listed in section 4 is manufactured in accordance with the technical documents listed in Appendix A of this certificate.
- (ii) The standards listed in section 9 of this certificate continue to satisfy the Essential Requirements relating to the design and construction of radio equipment given in the Articles of the Directive listed in section 8 of this certificate and the generally acknowledged state of the art (e.g. as determined by the publishers of those standards).

**SCHEDULE TO EU TYPE EXAMINATION CERTIFICATE**  
**ENW25RED0005**

**APPENDIX A - LIST OF TECHNICAL DOCUMENTS**

<b>Document/file name:</b>	<b>Rev. Level:</b>	<b>Issue date:</b>
TFA-1562	Rev. A	2025-04-15

