Oska Inc, 2725 Jefferson Street, #15A, Carlsbad, CA 92008

DECLARATION OF CONFORMITY

Effective Date:
November 16, 2022

DoC Valid during MDR-transitional period, 27 May 2024 to 31 December 2028.

Reviewed	Chip Currey Quality Manager	Chip Currey	Chip Currey (Jan 4, 2024 21:07 PST)	Jan 4, 2024
Reviewed	Product Manager	Evan Lindsay		Jan 4, 2024

Manufacturer:

Oska, Inc. DBA Oska Wellness
2725 Jefferson Street, Suite 15A, Carlsbad, CA 92008, USA
Tel: (+1) 844.630.9932

Product & GMDN:
Oska Pulse – 35169

Product Versions:
Oska Pulse 90-Minute
Oska Pulse From Your Doctor

Description & Intended Use:
The Oska Pulse product is a non-invasive pulsed electromagnetic field device designed for use alone or as an adjunctive therapy for improved healing of existing conditions, reduce inflammation, and as an additional therapy in treating osteoarticular inflammatory conditions, ie. arthritis.

Directives:
Directive 93/42/EEC Annex I Essential Requirements
Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)
Directive 2014/30/EU Electromagnetic Compatibility (EMC)

Classification:
Class IIa (Annex IX, Rule 9) of Community Directive 93/42/EEC, as amended Concerning Medical Devices

Conformity Assessment Route:
Annex II (excl. Section 4)

EC Representative:
Emergo Europe
~~Prinsessegracht 20, 2514 AP The Hague, The Netherlands~~
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
Tel: (+31) (0) 70 345.8570
Fax: (+31) (0) 70 346.7299

Update to EU Authorized Representative address.

Reviewed	Chip Currey Quality Manager	Chip Currey	Chip Currey (Jan 4, 2024 21:07 PST)	Jan 4, 2024
Reviewed	Product Manager	Evan Lindsay		Jan 4, 2024

Notified Body:
DNV AS - 2460
Veritasveien 3, 363 Høvik, Norway
Tel: (+47) 67 57 88 00EC
Certificate Number: 10000372922-PA-NA-NOR

Applicable Standards:

- EN ISO 13485:2016/AC:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- EN ISO 14971: 2019 Medical devices -- Application of risk management to medical devices
- EN 1041: 2014Information supplied by the manufacturer with medical devices
- EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied
- EN 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing
- EN 60601-1:2022/A2:2019 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-4:2017 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
- EN 60601-1-6:2020Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- EN IEC 62366:2015/AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- EN IEC 62304:2015/A1:2015 Medical device software - Software life cycle processes
- EN 60601-1-11:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN ISO 14155:2011/AC2011 Clinical investigation of medical devices for human subjects - Good clinical practice.

Declaration:

Oska, Inc., being manufacturer/distributor within the European Union hereby declare that the products covered by the declaration conform with the Essential Requirements of EC Directive 93/42/EEC and have been subject to the Conformity Assessment procedures defined in Annex II under the supervision of DNV AS, a Notified Body authorized by the Competent Authority, carrying the Notified Body Number 2460.

This declaration is valid for all devices described in this document.

The declaration is supported by EC Certificate of Quality Assurance issued by DNV AS Notified Body Number 2460, Certificate Number 10000372922-PA-NA-NOR.

Signed: *Greg Battle* Greg Battle (Nov 22, 2022 15:38 PST) Date: Nov 22, 2022

Name: Greg Battle

Title: Chief Executive Officer

Representative or designee
Oska, Inc. DBA Oska Wellness
2725 Jefferson Street, Suite 15A, Carlsbad, CA 92008, USA