Certificate

P000563123CRT01

First issue	07-Aug -2026	Re-certification	Not Applicable
Reissued	Not Applicable	Preceding cert.	Not Applicable
Valid until	07-Aug-2031		

EU Quality Management System Certificate – Annex IX

Conformity Assessment Based on a Quality Management System
and on Assessment of Technical Documentation
Regulation 2017/745 on MEDICAL DEVICES

For the Quality Management System of

Plasmacure B.V.

Regarding the scope EU quality management system for the following devices or groups of devices: MDA 0308 Active non-implantable devices for wound and skin care

This certificate is based on the following documents:
Audit reports: 21M00110RPT01, 24M00325RPT01, 25M00108RPT01 and 25M00117RPT01
TD reports: 23M00180RPT01

Kiwa Assurance B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX, chapter I and III and that the relevant provisions of the Regulation 2017/745 dated May 5, 2017 concerning Medical Devices are fulfilled. The validity of this certificate is Five (5) years and includes the surveillance obligations of Annex IX, section 3. The products shown in the scope of certification are covered by this certificate and may bear the CE marking using the Notified Body number "1912".

Signed by:
Joe Petersen
8A265E04DD41483...
Mr. J. Petersen
Certification Decision Maker

DocuSigned by:
Esther Brandsen- Rasing
3F5D86A06EBF427...
E. Brandsen- Rasing MBA BSc
Unit Manager

This certificate consists of 2 pages
Disclosure of the certificate is permitted

MDR 2017/745

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EAR: NA

Certificate

Appendix of EU Quality Management System Certificate – Annex IX

For the certificate P000563123CRT01

The scope of certificate comprises an EU Quality Management Assessment regarding the following device(s)

Devices	Risk classification	Marketed under tradename	Intended purpose (only IIb and III)
PLASOMA Pulser (PU02) PLASOMA Pad (C0801) Basic UDI-DI 08720589248PU02XD MDA 0308 Active non-implantable devices for wound and skin care Z12019003 – Wound treatment equipment	Devices in Class IIb	PLASOMA	PLASOMA cold plasma system is intended to be used as an adjunct therapy in wound care to improve wound healing for adult patients who have slow healing or non-healing wounds that have breached the dermis. PLASOMA cold plasma system is intended to be used by health care professionals with experience in wound management or wound treatment like (wound care) nurses or medical doctors active in wound care. The device can be used without specific user training. PLASOMA cold plasma system is intended to be used in professional healthcare facilities and in indoor home environments.

Revision history

Version	Changes
P000563123CRT01	Initial version

kiwa
MDR 2017/745

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