Docusign Envelope ID: C86ED0D9-1B1A-8A53-825E-2149A337962E

Certificate

# P000572190CRT01

| | | | |
|---|---|---|---|
| First issue | 30-Jul-2020 | Re-certification | 29-Jul-2026 |
| Reissued | 07-Jul-2026 | Technical Area | 1.2.E Active (non-implantable) medical devices other than specified above |
| Valid until | 29-Jul-2029 | Preceeding cert. | P000512079CRT01 |

## Quality Management System Certificate

EN-ISO 13485:2016

**For the Quality Management System of**

# Plasmacure B.V.

Regarding the scope Design, development, management of manufacturing, placing on the market of active medical devices for wound care

**This certificate is based on the following documents:**
P000572190RPT01

Kiwa Assurance B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 and that all requirements of the standard and its implementation are fulfilled.

The certificate validity is three years and includes the surveillance obligations of EN-ISO/IEC 17021-1:2015.

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

Signed by:
Dennis van der Vlugt
4F831C843C0B4EA...
Ing. D. van der Vlugt
Director

This certificate consists of 2 page(s)
Disclosure of the certificate is permitted

MGMT. SYS. RvA C 637

EN-ISO 13485:2016

2030 v1.19 | P000572190CRT01

**Kiwa Assurance B.V. (Kiwa Medical Certification)**
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The Netherlands

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Certificate

# Appendix of EN-ISO 13485 Certificate

**For the certificate P000572190CRT01**

**Organizational Boundary(ies)**

| Certified locations and/or organizations | Scope |
|---|---|
| Transistorweg 5<br>6534 AT Nijmegen, The Netherlands | Registered place of business but no activities |
| Transistorweg 7<br>6534 AT Nijmegen, The Netherlands | Management activities |
| High Tech Campus 11<br>5656 AE Eindhoven, The Netherlands | R&D activities |

**Revision history**

| Version | Changes |
|---|---|
| **P000572190CRT01** | Initial version |

MGMT. SYS. RvA C 637

EN-ISO 13485:2016

2030 v1.19 | P000572190CRT01

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