QUALITY POLICY

EUCEREP B.V. · EUCEREP LTD

EUCEREP B.V. — EU Authorised Representative
Roald Dahllaan 33, 5629 MC Eindhoven, Netherlands

EUCEREP LTD — UK Responsible Person
7 Meeting Lane, Tibbets Close, Alcester, Warwickshire, B49 5QU, United Kingdom

Document No.	Version	Effective date
PL-001	1.0	03 Nov 2026

Document Control

Approval

Role	Name	Signature	Date
Approved by — Managing Director (Top Management & Management Representative)	Hany Mahmoud	Hany Mahmoud	11/03/2026

Revision History

Version	Date	Description of change	Author
1.0	03 NOV 2026	Initial release.	Hany Mahmoud

This Quality Policy is a controlled document. The current authorised version is held in the QMS document register; printed copies are uncontrolled unless stamped as controlled.

EUCEREP is committed to providing regulatory representation and coordinated technical services to the medical device industry that consistently meet customer and regulatory requirements. We maintain the competence and integrity required of an EU Authorised Representative and UK Responsible Person, control our outsourced suppliers to safeguard the quality of services delivered on our behalf, comply with applicable regulatory requirements, and continually improve the effectiveness of our Quality Management System.From this perspective, Top Management ensures the following:

Regulatory Compliance: We adhere strictly to the EU Medical Devices Regulation (EU MDR 2017/745), the UK Medical Devices Regulations 2002 (as amended), ISO 13485:2016, and all relevant statutory mandates.

Competence & Expertise: We continuously develop the qualifications and training of our personnel and Person Responsible for Regulatory Compliance (PRRC) to preserve technical excellence and regulatory integrity.

Outsourced Service Control: We maintain robust oversight, evaluation, and qualification processes for all outsourced service providers to ensure seamless service quality.

Strategic Quality Objectives: To operationalize this policy, Top Management establishes and monitors measurable quality objectives at relevant functions and levels. Our current strategic commitments include:

1. **Certification Excellence:** Achieving and maintaining formal ISO 13485:2016 QMS certification through an accredited certification body.
2. **Service Scope Expansion:** Expanding our regulatory representation portfolio to include US Agent services for FDA compliance, including full SOP revision and client on boarding infrastructure.

This Quality Policy is made available to all employees via the shared folder, accessible to relevant interested parties upon request, and published on the company website. Furthermore, it is reviewed annually during Management Review meetings to ensure its continuing suitability and effectiveness.