



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
The Director

Brussels
SANTE.D.3(2026)/

Mr Ramtin Khoshnyat

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Your application for access to documents EASE 2025/6222

Dear Mr Khoshnyat,

We refer to your request registered on 27 November 2025 under the above-mentioned reference number.

You requested access to the following documents:

- EN 556-2:2024
Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
- EN ISO 10993-10:2023
Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
- EN ISO 10993-12:2021
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

Please note that the documents which form the subject-matter of your application EASE 2025/6222 may be obtained:

- for EN 556-2:2024, via the following link:
<https://harmonized.standards.eu/>;
- for EN ISO 10993-10:2023 and EN ISO 10993-12:2021, after logging in with your EU Login account, via the following link:
https://ec.europa.eu/growth/tools-databases/enorm/access_to_harmonised_standards.

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Yours sincerely,

Rainer BECKER

Enclosure: List of identified documents.

⁽¹⁾ Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).