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Privacy Notice - Pharmacovigilance

General information

Eurogine S.L. (hereinafter Eurogine) manufactures and markets medical devices for use in humans which are subject to safety monitoring.

This monitoring, known as pharmacovigilance, consists of recording and evaluating adverse events arising from the use of its medical devices, so that both Eurogine and the regulatory bodies can act and protect the health of users and patients.

Pharmacovigilance requires the processing of certain personal data, either from users or patients, in a way that directly or indirectly identifies the person related to/affected by a reported adverse event.

Purpose and legal basis

Personal data collected and processed in the context of Pharmacovigilance are subject to the provisions of the applicable data protection legislation and, in particular, Articles 6(1)(c) and 9(2)(i) of the EU General Data Protection Regulation (Regulation (EU) 2016/679).

All data shall be processed exclusively for Pharmacovigilance purposes including, if necessary, documentation, evaluation and notification to relevant third parties in accordance with the provisions of Pharmacovigilance.

Categories of personal data processed

The data that may need to be processed may relate to the patient who has experienced the adverse event and/or who has reported the adverse event.

Patients: The information they have provided, including, first name, surname and ID; date of birth, weight and height; information on health and sexual activity; details of the medical device involved and of the adverse event itself.

Subjects reporting the incident: The information they have provided to enable the regulatory authority to follow up, including name, profession, initials, address, email, telephone number and relationship to the patient.

Conservation period

Eurogine will use and store your personal data in accordance with legally required requirements for the retention and reporting of Pharmacovigilance information. These requirements oblige to maintain Pharmacovigilance information, which may include personal data, for at least the entire life cycle of the product and for such additional time as may be required by applicable law.

Information about your rights

For information about your rights regarding your personal data, you will find additional information at Privacy policy (eurogine.com). However, we inform you that your rights to your personal data may be limited for the purpose of compliance with pharmacovigilance obligations and provided that there is a legal basis for this.

Identity and contact details of the Controller of the Processing of your Personal Data

The data controller is EUROGINE, S.L., with CIF B-59608919 and registered office at c/ Raurell 21-29, Nave 3, 08860 Castelldefels, Barcelona, Spain.