

PRIVACY NOTICE FOR VIGILANCE

This Privacy Notice is intended to provide information on how Synthon International Holding B.V. and/or its affiliate companies in the European Economic Area (“Synthon” or “we”) collect, store, use and process your personal data for the purposes of activities related to vigilance.

For general information about data processing at Synthon, please visit [Synthon’s Privacy and Cookie Statement](#).

Synthon takes data privacy seriously and treats all your personal data in accordance with applicable data protection laws, which include, for the European Economic Area, the General Data Protection Regulation (GDPR; Regulation (EU) 2016/679).

What are personal data?

‘Personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR).

What is processing?

‘Processing’ of personal data means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (GDPR).

Why do we collect your personal data?

Any personal data provided to Synthon related to adverse events/incidents or other activities related to vigilance will be used solely for the purpose of monitoring of the safety of the medical devices. This information is very important for public health and will be used for the detection, assessment, understanding and prevention of adverse events/incidents or any other medical device-related problem.

We collect and process your data for these purposes in order to comply with our legal obligations (GDPR).

Who will see your personal data?

Synthon may share the data you provided among Synthon employees, business partners, service providers and Health Authorities worldwide in order to comply with vigilance legislation.

The reports contain details about the adverse events/incidents, but will only contain limited personal data. Of note, a patient’s name will not be provided.

Your personal information may be transferred to countries outside the European Economic Area. These countries may not have data protection laws that provide an adequate level of protection to your personal information. We therefore take steps to ensure that third parties

and Synthon's affiliated companies to whom we transfer data in those countries commit to guaranteeing an adequate level of protection for your personal information.

How long will we keep your personal information?

We will retain your personal information for the period required by law, which, for adverse events/incidents, is until at least 10 years after the last medical device has been manufactured (Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices).

What are your rights as data subject?

You have the right to

- Know that your personal data are being processed and for which purpose (GDPR);
- Request copies of those data (GDPR);
- Request rectification or erasure of your personal data if it is inaccurate or processed for purposes not stated above (GDPR);
- Request Synthon to restrict the processing of your personal data (GDPR);
- In certain circumstances, object to the processing of your personal data (GDPR);
- Request information on the identities or categories of third parties to which your personal data are transferred (GDPR);
- Lodge a complaint with the data protection authority in your country (GDPR).

Whom should you contact for more information or for exercising your rights on the processing of personal data by Synthon?

Please direct any questions and requests related to the processing of personal data to:
Synthon International Holding B.V.

Attn: Privacy officer

P.O. Box 7071

6503 GN Nijmegen

The Netherlands

E-mail: dataprivacy@Synthon.com