

Dear Customers,

According to the regulations (EU) 2017/745 and (EU) 2017/746, applicable German laws and our SCC (see “Special Certification Conditions (SCC) of DEKRA Certification GmbH for the Business Unit Medical Devices”) reportable incidents and FSCA (Field Safety Corrective Action – hereafter abbreviated as “report”) have to be reported to the competent authority (e.g. BfArM) as well as to DEKRA Certification GmbH.

Please submit your notifications to the following centralized email address:

Incident.certification.de@dekra.com.

Your obligation to notify the competent authority (or authorities) is not affected by this system.

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1. Purpose

This information sheet describes the procedure for reporting notifications relating to medical devices and QM systems which are certified by DEKRA Certification GmbH.

2. Reference documents and legal requirements

- Regulation (EU) 2017/745
- Regulation (EU) 2017/746
- Applicable German laws
- Specific Certification Conditions (SCC) of DEKRA Certification GmbH for the business field of medical devices

3. Abbreviations and definitions

See Regulation (EU) 2017/745/Regulation (EU) 2017/745 Article 2

4. Documents to be submitted to DEKRA Certification GmbH

- Information letter about the recall;
- Initial notification and Final notification
Any follow up report(s); If appropriate, technical inspection report(s) (as .pdf files);

5. Notification Manner

Via email

6. Requirements for the electronic notification

Important note:

Please send different incidents **separately** in an email to DEKRA Certification GmbH.
Documents or files with related content must be combined in one email each time.

a) Recipient of the email:

Incident.certification.de@dekra.com

b) Reference line of the email:

Registration number of the incident given by BfArM or other national authority.

Examples:

Reference line: [BfArM case no. 0000/08 \(our ref. # 001\) initial notification](#)

c) Attachments to the email:

See point 4

d) Text of the email:

Not required unless you wish to provide a note, comment, or additional explanation about the incident.

7. Confirmation of receipt

You will receive an automatic confirmation of receipt by mail from DEKRA Certification GmbH.

The recording and evaluation of the incident report will be charged according to our current price list.