Processing of incident notifications, recalls, FSCA and FSN to DEKRA Certification GmbH

Dear Customers,

We would like to inform you that in accordance with the Directives MDD 93/42/EEC, MPG, MPSV and our General Terms and Conditions of Business (see “special conditions for the conducting of certification of quality management systems in the medical sector”) both the authorities responsible (e.g. in Germany the BfArM [Federal Institute for Drugs and Medical Devices]) and DEKRA Certification GmbH are to be notified of incidents, recalls, FSCA and FSN (abbreviated as notifications in the following) subject to mandatory notification.

We take customer satisfaction extremely seriously and endeavour to improve it where we can. In order to ensure a better service for the processing of notifications we have introduced for you an electronic notification system.

To transmit your notifications we have set up a centralised email address

Incident.certification.de@dekra.com.

The benefit for you is, firstly, that the system simplifies the notification process to DEKRA Certification GmbH. Secondly, it will greatly reduce the processing time. Also as regards environmental friendliness and costs - paper and postage – the electronic notification system provides you with several important advantages.

Your obligation to notify the authorities responsible is not affected by this system.

Please use the above-mentioned email address, which you can use for all your correspondence concerning notifications.

The following explains the notification procedure more thoroughly and details the individual stages.

Please do not hesitate to contact us in case of any further queries about our notification system!

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1. Purpose of the email notification

This info sheet describes the procedure for notifying of incidents, recalls, FSCA and FSN for medical products and QM systems certified by DEKRA Certification GmbH.

The following notification procedure simplifies the work involved in notification (no registered mails, faxes or other paper notification). The aim of the notification procedure is to provide a more efficient system which greatly reduces the processing time.

2. Reference documents and legal requirements

- Directive MDD 93/42/EEC
- MPG (Medizinproduktegesetz [Medical Product Act])
- MPSV (Medizinprodukte-Sicherheitsplanverordnung) [Medical Products Safety Plan Ordinance]
- General Terms and Conditions of DEKRA Certification GmbH

3. Abbreviations and definitions

BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Devices
MHRA	Medicines and Healthcare products Regulatory Agency
First notification	Initial report of an incident/ recall/ FSCA/ FSN (to BfArM or other country-specific authorities)
Final notification	Final report on the notified incident/ recall/ FSCA/ FSN with details of any measures and corresponding timetable (to BfArM or other country-specific authorities)
Incident	Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.
Recall	A corrective action initiated by the manufacturer which lead to a return, exchange, modification or refitting, the segregation or destruction of a medical device
FSCA (Field Safety Corrective Action)	Action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a FIELD SAFETY NOTICE
FSN (Field Safety Notice)	A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action (FSCA).

4. Documents to be submitted to DEKRA Certification GmbH

§ Copies of the first and final notification and concluding reports requiring mandatory notification both as .doc as well as .pdf files;
§ Copies of the interim reports and, if appropriate, technical inspection reports (.pdf);
§ All correspondence regarding the notification with authorities such as BfArM, MHRA and other country-specific authorities (.pdf).
Should several authorities be simultaneously involved, the complete correspondence with one authority is sufficient (preferably BfArM or another leading authority cited). Irrespective of this, however, DEKRA Certification GmbH reserves the right to access the correspondence with the other authorities as required.

5. Notification Manner

Email

6. Requirements for the email notification

Important note:

Related documentation or files are to be comprised in one email.

Please send different cases separately in an extra email to DEKRA Certification GmbH.

a) Recipient of the email:

Incident.certification.de@dekra.com

b) Reference line of the email:

Registration number of the incident given by BfArM, MHRA or other country-specific authority, if applicable, the internal customer reference number of incident, reason of content of incident.

Examples:

Reference line: BfArM case no. 0000/08 (our ref. # 001) initial notification
or Reference line: BfArM case 0000/08 recall of product „XY“

c) Attachments to the email:

Please refer to point 4
Please note:
both Initial and final reports should to be sent as .doc and .pdf files
(each file in 2 formats / versions)

d) Text of the email:

Not necessary, but welcome if you wish to give more information or explanation regarding the incident.

7. Confirmation of receipt

Confirmation of receipt is generated automatically by DEKRA Certification GmbH for every notification received and sent to the sender.

For the required effort, we charge a rate of 170,00 € per notification.

Should you not receive confirmation of receipt or have any other queries regarding the notification, please contact Mrs. Melanie Sommer
phone no. +49.711.7861-3442.