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 “specific certification conditions (SCC) of DEKRA Certification for the business field of medical devices”) the authorities responsible (e.g, in Germany the BfArM [Federal Institute for Drugs and Medical Devices]) as well as DEKRA Certification GmbH have to be notified about incidents, recalls, FSCA and FSN (hereafter abbreviated to/referred to as “notifications”).

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

To transmit your notification reports we have set up a centralised email address:

Incident.certification.de@dekra.com.

The main benefit for you is that this system simplifies the notification process to DEKRA Certification GmbH. In addition, it will greatly reduce the processing time. Furthermore the electronic notification system provides you with several important advantages in terms of environmental impact and costs for paper and postage.

Your obligation to notify the responsible authorities is not affected. Please beware that you still need to notify other relevant authorities as this system is only for informing DEKRA Certification GmbH.

Please use the email address above for all your correspondence concerning incidents.

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

We are happy to support you if you have any further queries about our notification system.

1. Purpose of the email notification

This guideline describes the procedure for notifying 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 recorded deliveries, faxes or other paper notification). The efficient sequence 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
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten / Central Office of the Federal States for the Health and Safety of Pharmaceuticals and Medical Devices
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 labelling 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 deselection or destruction of a medical device
FSCA (Field Safety Corrective Action)	Action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device which is already on the market. Such actions, whether associated with direct or indirect harm, should be reported and notified via a FIELD SAFETY NOTICE
FSN (Field Safety	A communication to customers and/or users sent out by a

Notice) manufacturer or its representative in relation to a Field Safety Corrective Action (FSCA)

4. Documents to be submitted to DEKRA Certification GmbH

- The letter informing the relevant parties of the recall
- Copies of the first and final notifications and the concluding both as .doc and .pdf files
- Copies of the interim reports and, if appropriate, technical inspection reports (.pdf)
- All correspondence with authorities such as BfArM, MHRA and other country-specific authorities (.pdf) relating to the notification
  If several authorities are simultaneously involved, the complete correspondence with a single authority is sufficient (preferably BfArM or another leading authority). Irrespective of this, DEKRA Certification GmbH reserves the right to access the correspondence with the other authorities as needed.

5. Notification Manner

Electronically by email.

6. Requirements for the email notification

Important note:

Related documentation and files have to be collected and sent together in one email.

Please send separate cases in separate emails 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 or 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 the initial and final reports must each 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 and sent to the sender by DEKRA Certification GmbH for every notification received.

We charge a standard fee according to our current price list to cover our administrative costs.