IME-DC GmbH | Fuhrmannstraße 11 | 95030 Hof | Germany

Foxmedica export s.r.o.
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Czech Republic

Hof, Germany, 15.04.2021

Urgent Safety Notice
Recall of Blood glucose test strips iDia (FSN 98-210311)

Dear Mrs Pyciak

We, IME-DC GmbH, set highest quality standards and therefore feel obliged to report any abnormalities that occur while using our products.

Herewith, we are informing you of a problem that may affect certain batches of iDia blood glucose test strips that were delivered to you.

As part of our constant quality control and market surveillance, we have located some test strip lots with possibly false low glucose readings. The use of these batches can lead, by determining false low glucose readings and mainly in insulin-dependent diabetics (if not recognized and the therapy is adjusted at the same time / the amount of insulin is slightly reduced), temporarily to slight hyperglycaemia.

Corresponding symptoms are increased thirst, increased need to urinate, abdominal pain, low blood pressure, tiredness and fatigue.

List of affected batches of blood glucose test strips iDia

selling unit 50 pcs.			
Batch	Expiry Date	Delivery Note No	Delivery Date
GSC0311B1	2022-01	LS147453	21.08.2020
GSD0315A2	2022-03	LS149086	09.10.2020
GSF0316A4	2022-03	LS150093	11.11.2020

Since patient safety is our highest priority, we ask you:

1.) To check whether you have one or more of the listed batches in stock and ask for the batches to be blocked. Please do not supply these batches anymore.

2.) To initiate the necessary regulatory steps and to contact the competent authority if it has not contacted you already.

3.) To translate the enclosed customer letter with respective specific requirements by your site and forward it to your customers.

4.) To collect the goods returned by the customers and to block them as well.

5.) To fill in the response (FSN Distributor reply EN 98-210311) as soon as the recall has been completed and send it back to us.

6.) To dispose the blocked affected items with respective record by supervisory authority after completion

We have carefully investigated the problem to find the cause of the possible error and have taken the appropriate corrective action.

We know that this measure can mean additional expense and hope for your support in conducting the recall.

If you have any questions, please do not hesitate to contact Mr Matthias Stark at +49 151 51 15 52 51 or by e-mail: matthias.stark@imedc.de

We deeply regret this situation and apologise for any inconvenience this will cause.

Yours sincerely,

IME-DC GmbH

Thomas Kispert

(Deputy safety officer for medical devices)

Dr. Stephanie Roloff

(Head of Quality Management)