CHELLES 17 June 2019

To the materials vigilance officer
To be used internally and sent to pharmacies

Recall on ADVANCE model crutches
Batches produced from January to March 2018 and May to August 2018
Marking: **01 to 03/2018** and **05 to 08/2018**

01	02	03	04	05	06	07	08
Recall			**Batch recalled already on 23 July 2018**	**Recall**			

Dear Sir/Madam,

HERDEGEN is committed to putting medical devices that guarantee patient safety on the market.

The ADVANCE crutches are considered as class I medical devices: they meet the requirements of the CE marking according to the 93/42/EEC directive and comply with the ISO 11334-1 standard. This elbow crutch is a technical aid to overcome temporary or

permanent mobility deficiency. The breaking of the handle or antebrachial support can lead to a loss of balance and risks of falling for the patient.

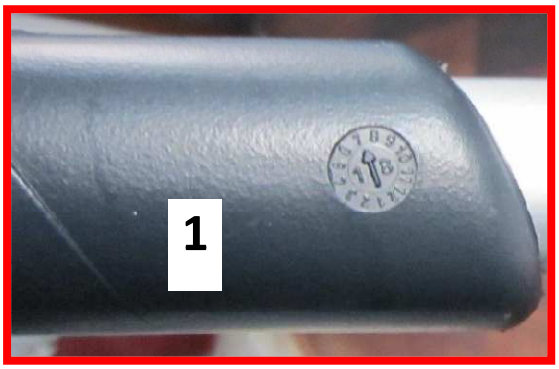
To follow up the batch 04/2018 recall (safety information available on the ANSM website at the following address: https://ansm.sante.fr/S-informer/Informations-de-securite-Retraits-de-lots-et-de-produits/Canne-anglaise-Advance-bi-matiere-Etablissements-Herdegen-Rappel), concerning the ADVANCE crutch, it appears that crutches from production batches January to March 2018, and May to August 2018 were the subject of limited additional claims.

The preventive and corrective actions taken during this period came fully into effect from 09/2018 batch included. No claim similar to the previous period has been recorded, confirming the actions taken.

We are concerned about the patients' expectations and the adequacy of the products for the intended uses. After consulting with the French ANSM, we have decided to recall other batches produced from **January to March 2018** and from **May to August 2018** in order to avoid any possible deficiency risk linked to the quality of our crutches.

Only crutches with a single production date are concerned (see figure 1). Crutches with a double production date (implemented since September 2018, see figure 2) are not concerned by this recall.

This letter is addressed to the distributors identified as having received the batches concerned. If you have sold or given some of these crutches to other distributors or retailers, please send them this information.



Batches 01, 02, 03, 05, 06, 07 and 08/2018
Only 1 production date

Non-recalled product example

The French ANSM has been informed of this recall.

Dominique DRUTEL

Materials vigilance officer

For any question regarding this recall, please contact our Customer Department (0033 2 48 23 84 50) or our Quality Department (qualite@herdegen.fr)

ADVANCE CRUTCHES RECALL (batches from 01 to 03/2018 + 05 to 08/2018)

Acknowledgment / answer letter to fill in and to return
no later than 31 July 2019.

I confirm we have checked the ADVANCE crutches stock in our possession and informed the pharmacies concerned.
Please check below the topics corresponding to your situation and indicate the quantities concerned :

☐ We have no crutches from the 01 to 03/2018 or 05 to 08/2018 batches because:

☐ These batches have not been received by our company

☐ All the crutches from the 01 to 03/2018 and 05 to 08/2018 batches have been distributed ; **Please indicate the number:**

☐ We have identified crutches corresponding to the 01 to 03/2018 and 05 to 08/2018 batches ; **Please indicate the number:**

Distributor name.....

Account number .....

Writer name.....

Function.....

Date.....

Signature

Please fill in this form and send it back to our Quality Department by email to: qualite@herdegen.fr