Wirz Ortho Mechanics
Dr. Peter Wirz
Bernstrasse 1

3076 Worb

Bern, 12 mai 2015

Notification according to Art. 6 MepV[1] dated 07.05.2015 regarding LegholderRX / Legholder

Acknowledgement of receipt

Dear Madam, dear Sir,

We have received the notification of the above-mentioned product and numbered it as shown below:

Notification No.: CH-201505-0035	Medical Device Class I

The notification duty according to Art. 6 MepV for this(these) medical device(s) has therefore been fulfilled.

Confirmation that the notification has been received according to Art. 6 MepV does not, however, constitute either an attestation of conformity, or an officially examined registration, or an assessment of the quality of the device. It is a confirmation that Swissmedic has noted that the above mentioned Class I medical device(s) has(have) been placed on the market. It is presumed that

[1] Medical Devices Ordinance of 17 October 2001 (Status as of April 15th 2015); SR 812.213

the person or entity placing the device on the market has provided the required clarifications in order to define the device's conformity according to the MepV.

We draw your attention to the fact that you are notably responsible for carrying out your own controls (Art. 14 MepV, self-control) and for notifying Swissmedic of serious adverse events, recalls and other safety measures (Art. 15 MepV).

Yours sincerely,

Swissmedic, Swiss Agency for Therapeutic Products
Division Medical Devices

S. Dunkel-de Raad

Saskia Dunkel-de Raad, PhD
Inspector

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