

SANKOM SA
Mr. R. Sanchez
Rue de la Molière 2
P.O Box 680
2800 Delémont

Bern, March 24, 2017

Notification according to Art. 6 MedDO¹ dated 20.03.2017 regarding Sankom Patent Socks

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-201703-0009	Medical Device Class I
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The notification duty according to Art. 6 MedDO for this (these) medical device(s) has therefore been fulfilled.

Confirmation that the notification has been received according to Art. 6 MedDO 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

¹ Medical Devices Ordinance of 17 October 2001; SR 812.213

that 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 MedDO.

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

Swissmedic has uploaded the notification information to Eudamed, the European Data-bank on Medical Devices.

Yours sincerely,

Swissmedic, Swiss Agency for Therapeutic Products
Division Medical Devices

A handwritten signature in blue ink, appearing to read "A. Drapela".

Aurélie Drapela
Scientific Officer