

MSP Medizintechnik GmbH Würtzlerstraße 16 A-1030 Wien

Rudolf Heintel Gesellschaft mbH
Erdbergstraße 166
1030 Wien

FSN – FIELD SAFETY NOTICE

Product name: HSO SafeHeat Hand Warmer,
Product Number: HSOWHAND01 or in a set with heating pad
Product Name: HSO SafeHeat Set, Product Number: HSOSAFEHESET
Affected Lot / Batch Number: All

Dear customers and sales partners,

Concerning the above-mentioned product, we have received reports of an incident on the basis of which we request that you inform your end customers in writing about the following (please send proof of customer information):
Prolonged body contact with the NON-INSULATED side (= viewed from the heating pad, the side pointing away from the hand) of the hand warmer may cause redness or burns. It should be noted that only the insulated side (= viewed from the heating pad, the hand-facing side) is intended for body contact.

When using the above-mentioned product, the following must also be noted:

- The intervals and comprehensiveness of the visual inspections must be selected individually according to patient / storage.
- Care should be taken to avoid heat build-up (for example through clothing or other blockage of heat dissipation).

We are in close consultation with the production and will advise you of any further measures, e.g. a possible addition to the warnings in the IFU, in order to keep you informed.

Thank you for your understanding and kind regards,

A handwritten signature in blue ink, appearing to read 'M. Pöltenstein'.

Markus Pöltenstein
General Manager
Rudolf Heintel Ges.m.b.H