

MEMO



To Whom it may concern,

Date: 7 October 2013

Hypoallergenic Ambu electrodes

The term hypoallergenic describes items that can cause or are claimed to cause fewer allergic reactions compared to other similar device.

Ambu criteria to claim hypoallergenic

A product can be claimed hypoallergenic when the product OR all materials with direct contact fulfill the following 3 requirements:

1. Passed *in vivo* biocompatibility studies (irritation and sensitization).
2. Demonstrated no presence of substances known to cause allergic reactions OR a comprehensive toxicological safety assessment of potential allergenic substances exists and demonstrate levels below toxicological relevant limits.
3. Long history of safe use (<5 ppm related to skin sensitizing within the last 3 years and more than 100.000 products sold) AND/OR no indication of sensitizing response observed in comprehensive clinical studies.

If "Repeated insult patch test on humans" are available, none of the above listed requirements are necessary.

Hypoallergenic electrodes

Following Ambu electrodes pass the above criteria and can be considered hypoallergenic:

Electrodes	Statement
BlueSensor BR, BRS, NF, L, VL, VLC, M, N, P, Q, QR, R, SP, T	DSC-018433
WhiteSensor 4841P, 4831Q, 7841P	DSC-018431
WhiteSensor Neonatal 40554, 40556, 40713	DSC-018432
WhiteSensor Tab (0215M, 0315M, 0415M, 0615M and 0715M)	DSC-018434
WhiteSensor 4500M, 4500M-H, 4530M, 4535M, 4540M, 4560M, 4570M	DSC-018435
Neuroline 700, 710, 714 (Neuroline Ground), 715, 720, 725	DSC-019536 DSC-019435

7/10-2013

Annette Bitz
Clinical Research and Sr.
Biosafety Specialist,
Ambu A/S

7/10-2013
Andrew Boey
Clinical Research and
Biosafety Specialist,
Ambu A/S