LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Date: 9 March 2011 Dnr: 24:2010/518112

Certificate[1)]

Manufacturer: Orifice Medical AB
Address: Aktergatan 2, 4 och 5
SE- 271 55 Ystad
Sweden

It is certified that:

The manufacturer is licensed in Sweden, and that the production has been and is being carried out under competent management, all in accordance with the Medicinal Products Act (1992:859) governing the importation, manufacture and distribution of such products in Sweden.
Manufacturing licence: 24:2009/510780.

The manufacturing plant is subject to inspections at regularly intervals.
Last inspection was conducted 15-17 September 2010.

The authorisation applies to:
1. Primary packaging
   Solid dosage form, tablets and capsules
2. Secondary packaging and labelling
3. Importation of herbal remedies for topical application
5. Batch release

The manufacturer conforms to requirements for good practices in the manufacture and quality control, as recommended by the World Health Organization and European Directive 2003/94/EC in respect of products to be sold or distributed within the country of origin or to be exported[2)].

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of the inspection, after which time the issuing authority should be consulted. The authenticity of this certificate may be verified with the issuing authority.

On duty

Tor Gråberg
Chief Pharmaceutical Inspector

Certification fee 950 SEK

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1. WHA 28.65 (see official Records No. 226, Annex 12, Part 1).
2. The requirements for good practices in the manufacture and quality control of drugs mentioned in the certificate refer to the text adopted by the Twenty-eighth World Health Assembly in its resolution WHA 28.65

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