

Franz Mensch GmbH . Gewerbering 20-21 . 86922 Eresing




To Whom It May Concern:

Certificate of Compliance
for all single-use medical products

The undersigned Franz Mensch GmbH, having its legal, administrative sites in
Gewerbering 20 – 21,
86922 Eresing (Bavaria),
Germany,

herewith declares that:

- a. Franz Mensch GmbH **medical disposable caps, gloves, face masks, disposable gowns, mattress covers, washing gloves, disposable blankets, coats, aprons and oversleeves (Hygostar and Hgonorm itens)** bear the  **Marking** according to the MDD 93/42/EEC (European Council Directive concerning medical devices), which allows their free distribution, sale and circulation in EEC.
- b. The above devices are manufactured, tested and released according to the Company's G.M.P.s, under the control of the implemented Quality System.
- c. According to the MDD 93/42/EEC-Annex V, the a.m. devices are classified by the manufacturer in **class I**.
- d. The production facility of Franz mensch GmbH has a Quality System that complies with recognised quality management and quality assurance standards: it is certified according to ISO 9001 (TÜV Certificate Registr. No. 01 100 090268, Report No. 090268).

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Valid until: 19.05.2015

Franz Mensch GmbH, Eresing, 11.06.2014



Axel Theiler, Managing Director