



**Art.no.: 2211**

**Dexamethasone, micronized, API**

**Residual Solvents Statement (EMA/CHMP/ICH/735038/2018, ICHQ3C)**

we hereby confirm that the product complies with the current edition of the ICH-Q3C guideline for residual solvents.

**BSE Statement (Note (EMA/410/01 Rev. 3))**

we hereby certify that the product was manufactured without materials from animals where there is a risk of BSE. A BSE risk assessment is therefore not required.

**GMO Statement (EU-regulations 1829/2003 and 1830/2003)**

we hereby confirm that the product is not subject to labeling and according to the Genetic Engineering Ordinance and can be labeled as "free from genetically modified organisms".

**Elemental Impurities Statement (EMA/CHMP/ICH/353369/2013, ICHQ3D)**

we hereby certify that the above mentioned raw material complies with the concentration limits for elements as defined in the ICH Guideline Q3D on elemental impurities.

**Nitrosamine Statement (Article 5 (3) of Regulation (EC) No 726/2004)**

We have supplier/manufacturer certificates available on request.

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