MANI, INC.
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April 16th, 2024

SVHC and CMR Substances

Product – Suture Needle: MANI Eyeless Surgical Needle

We declare that, to the best of our knowledge, the subject product does not contain any of the following surveyed substances, either intentionally or in excess of the prescribed thresholds [*1]. This is based on information provided by the raw material supplier and not on the results of analytical tests.

Surveyed substances:

- SVHC (Substances of Very High Concern) [*2]
- CMR (Carcinogenic, Mutagenic, Reprotoxic) Substances [*3][*4] (except Cobalt (CAS No.:7440-48-4)[*5])

[*1] If no threshold is set, 0.1 wt% shall be the threshold value.

[*2] REACH; Article 57 and 59(10) of Regulation (EC) No 1907/2006
Candidate list of substances (240 substances of range up to30th SVHC, last update: 23-Jan-2024).

[*3] Medical Device Regulation (MDR); Art 10.4 of Annex I of REGULATION (EU) 2017/745
substances which are CMR, of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1),

[*4] CLP; Part 3 of Annex VI to Regulation (EC) No 1272/2008
Substances of range up to CLP ATP20 (it shall apply from 1 February 2025)

[*5] Cobalt may be present as an impurity of max 1% in the stainless-steel component, which is the main material of the subject product.

We accept no liability for matters arising from or in connection with this information. Medical device manufacturers must determine the suitability of a material and the device using that material for a particular application after appropriate testing and evaluation. They are also responsible for ensuring that the device using the material is safe and effective for the prescribed use and complies with regulatory requirements.