Certificate of Conformity

Article no.	Retrace Code/Batch/Lot no.
292483005	16910/21

Article description
DURAN® PTFE coated GL 45 Silicone Septum for piercing Platinium catalysed VMQ)

Regulatory compliance (PTFE-coated silicone cap liner)

The PTFE-coated vinyl-methyl-silicone (VMQ) cap liner conforms to the following standards:

Raw material Silicone (VMQ)

- FDA CFR 21 Part 177.2600
- BfR Recommendation XV

Raw material Polytetrafluoroethylene (PTFE)

- FDA CFR 21 Part 177.1550
- BfR Recommendation LI

Statement on BSE/TSE

We confirm that the raw material used in the manufacture of the referenced product is not of animal origin. Accordingly, transmission of animal spongiform encephalopathy agents via the mentioned components is extremely improbable. We therefore state that these materials and the product is to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

Certified by: Mariska Jefferson, Quality Manager

Date of issue: 2022-09-23

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