

VOGT MEDICAL | RÜPPURRERSTR. 1A HAUS B | 76137 KARLSRUHE | GERMANY

To whom it may concern

Karlsruhe, 29.07.2020

VM High risk examination gloves

Dear Sir or Madam,

We, Vogt Medical Vertrieb GmbH, situated Rüppurrer Str. 1A, Haus B, 76137 Karlsruhe, Germany, Commercial Register No. HRB 108246 herewith would like to declare that our VM High risk examination gloves are considered as a medical device to be used for conducting medical checkups, diagnostic and therapeutic procedures and for handling contaminated medical material in condition of increased risk of infection. It is classified as Class I product of the Medical Device Directive (MDD) 93/42/EEC. They are meet the requirements of EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ASTM D3578-19 and ISO 11193:2008. It is also confirmed with ISO 9001:2015 No. 12 100 26 693 TMS, EN ISO 13485:2016 No. Q5 17 0857 451 038 certificates which have been given out by certified body TÜV SÜD Management Service GmbH.

VM High risk examination gloves must have the following physical dimensions:

| Size | XS | S | M | L | XL |
|---------------------------|----------|-------|-------|--------|------|
| Length (mm) | 290 | 290 | 290 | 290 | 290 |
| Palm width (mm) | ≤80 | 80±10 | 95±10 | 110±10 | ≥110 |
| Thickness of palm (mm)* | Min 0.13 | | | | |
| Thickness of finger (mm)* | Min 0.20 | | | | |

Based on the investigation of control samples, the length, width and thickness of the gloves meet all the relevant requirements of EN 455 and ISO 11193

Best regards

Galina Kulgunina
Head of Quality and Regulatory Department
VOGT MEDICAL Germany

