

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

To whom it may concern

Karlsruhe, 31.07.2020

VM Latex examination gloves standard

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 Latex examination gloves standard are considered as a medical device.

It is classified as Class I product which according to the Medical Device Directive (MDD) 93/42/EEC amended by Council Directive 2007/47/EC. They are meet the requirements of EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 and ASTM D3578 – 05 (2015).

It is also confirmed with ISO 9001:2015 No. 12 100 26 693 TMS. Q5 17 0857 451 038 which have been given out by certified body TÜV SÜD Management Service GmbH.

Best regards

Galina Kulgunina
Quality Assurance & Regulatory Affairs Manager
VOGT**MEDICAL** Germany

