

EU DECLARATION OF CONFORMITY

THE MANUFACTURER:

SHOWA Glove Co. 565 Tohori,
Himeji Hyogo 670 - 0802 Japan

THE AUTHORIZED REPRESENTATIVE WITHIN THE EUROPEAN ECONOMIC AREA:

SHOWA International (Netherlands) B.V WTC -
Tower I - Strawinskylaan 1817 1077 XX
Amsterdam The Netherlands

DECLARE THAT THE PRODUCT LISTED AS **SHOWA S-TEX 581** IS IN CONFORMITY WITH THE PROVISIONS OF

- EN 420:2003+A1:2009
- Regulation EU 2016/425
- Annex II: essential health and safety requirement



The notified body SGS Fimko Oy - no. 0598 performed the EU Type Examination (Module B) - and issued the EU type examination certificate no FI18/962489

The glove is subject to the ongoing conformity assessment procedure and is under surveillance of the notified body SGS Fimko Oy - no. 0598.

Basic UDI-DI
4907920017P
Single Registration Number
JP-MF-000001567

CONFORMITY ASSESSMENT, MEDICAL DEVICE REGULATION 2017/745, EXAMINATION GLOVES
Device Classification: Class I, Rule 5
Route to Compliance: Annex II and III of MDR 2017/745
Applied Harmonized Standards: EN 455-1, EN455-2, EN 455-3, EN 455-4



YASUSHI OKADA
Manager EMEA
Products & Logistics

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