



MDSS GmbH · Schiffgraben 41 · 30175 Hannover · Germany

Sri Trang Gloves (Thailand) Public Company Limited
Nattawut Promthong
10 Soi 10, Phetkasem Road,
Hat Yai, Songkhla 90110
THAILAND

+49 511 62628630
info@mdssar.com
www.mdssar.com

2021.02.04

Complaints Summary: January 01, 2020 to December 31, 2020

Manufacturer: Sri Trang Gloves (Thailand) Public Company Limited

MDSS acts as European Authorised Representative (EC REP) on behalf of the manufacturer, Sri Trang Gloves (Thailand) Public Company Limited. MDSS, as the EC REP, is not involved in the sales and distribution of medical devices. The authorised representative is defined in Article 1. 2 (j) of the Medical Device Directive (MDD) 93/42/EEC.

"authorised representative means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive"

The EC REP must be available to and can be contacted by a European authority instead of the manufacturer. The MDD 93/42/EEC furthermore outlines that the name and address of the EC REP shall be disclosed on the label, or the outer packaging, or instructions for use.

"...devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;..."

Consequently, MDSS could also be contacted by customers located in the European Economic Area and Switzerland.

MDSS has appropriate procedures in place to handle feedback from the European market and any complaints are forwarded directly to the manufacturer, Sri Trang Gloves (Thailand) Public Company Limited, upon receipt.

Regarding the above manufacturer and time period

- MDSS received:
 - 0 vigilance events (incidents and field safety corrective action)
 - 0 customer complaint(s) concerning alleged deficiencies related to safety or performance.
 - 3 competent authority market surveillance inquiries.

Medical Device Safety Service GmbH

This letter is created electronically and is valid without a signature.

MDSS GmbH · Medical Device Safety Service GmbH

Handelsregister Hannover HRB 57318 · Amtsgericht Hannover
Trade Register Hannover HRB 57318 · Local Court Hannover

USt-IdNr: DE177346163
VAT ID: DE177346163

Geschäftsführer: Ludger Möller
President: Ludger Möller

Sparkasse Hannover

S.W.I.F.T.: SPKHDE2H
IBAN: DE24 2505 0180 0910 0792 77

Commerzbank AG, Hannover

S.W.I.F.T.: COBADEFF 250
IBAN: DE67 2504 0066 0338 8816 00

