ulma International GmbH
Alfred-Nobel-Str. 5
50226 Frechen
Deutschland / Germany

EC DECLARATION OF CONFORMITY

- Declaration as Medical Device, Class IIa -

The authorized European representative

ulma International GmbH
Alfred-Nobel-Str. 5
50226 Frechen
Deutschland / Germany

SRN (Single Registration Number): DE-AR-000010015

declares on his sole responsibility, that the following described products

Item code	Description	Size
1202010	*Maxitex Ortho*	*6,0*
1202011	*Maxitex Ortho*	*6,5*
1202012	*Maxitex Ortho*	*7,0*
1202013	*Maxitex Ortho*	*7,5*
1202014	*Maxitex Ortho*	*8,0*
1202015	*Maxitex Ortho*	*8,5*
1202016	*Maxitex Ortho*	*9,0*

Type: *Surgical glove, sterile, powder-free, brown, class IIa*
Basic-UDI-DI: *955507611080H7*
LOT-number: *See packaging*

manufactured by:

TERANG NUSA (MALAYSIA) SDN. BHD.
2, Jalan 8, Pengkalan Chepa 2, Industrial Zone
16100 Kota Bharu
Kelantan
MALAYSIA

SRN (Single Registration Number): MY-MF-000023462

Notified Body:

Issuer: *TÜV SÜD Product Service GmbH (0123)*
Cert. No.: *G10 061155 0020 Rev. 00*
Valid until: *26.08.2029*

meet the provisions of Regulation (EU) 2017/745, as amended and supplemented.
The conformity assessment has been carried out in accordance with Annex IX, Chapter I and III.
The products are certified in accordance with the classification rules of Regulation (EU) 2017/745 Annex VIII as a medical device of class class IIa.

With regard to the use and utilization of the above mentioned product, we emphasize, that the instructions for use (see labelling on packaging) as well as the appropriate application and safety rules shall be followed in particular.
The user of the products bears the sole responsibility caused by improper usage or other than the intended use.
In terms of the evidence of conformity all relevant documents are filed in our premises in accordance to current regulations and available for the authorities at any time.

Issuing date: *10.03.2026*
Expiry date: *26.08.2029*

ulma
Alfred-Nobel-Str. 5
50226 Frechen
info@ulma.de

(Signature and company stamp)

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