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

EU DECLARATION OF CONFORMITY

- registered as PPE Category III -

The authorized European representative

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

declares that the Personal Protective Equipment (PPE) described hereafter

Article no.	Product reference	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*

Description: *Surgical glove, sterile, powder-free, brown, category III*

is in conformity with the provisions of Regulation (EU) 2016/425 and, where such is the case with the national standard transposing harmonized standards

| EN ISO 374-1:2016+A1:2018 / Type B | EN 374-2:2014 | EN 374-4:2019 | EN 374-5:2016 |
| EN 21420:2020 | EN 16523-1:2015 | EN 421:2010 |

is identical to the PPE which is the subject of
EU Type-Examination certificate number: 2777/10569-03/E00-00, issued by

SATRA Technology Europe Ltd
Bracetown Business Park
Clonee, DIS YN2P
Ireland

is subject to the procedure set out in Annex VII (Module C2) of the Regulation (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Ltd. - European Notified Body 2777 .

With regard to the use and utilization of the above mentioned product, we emphazise, 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: *10.12.2025*
Expiry date: *26.05.2028*



(Signature and company stamp)

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