

EU Declaration of conformity

CE2777

This declaration of conformity is issued under the sole responsibility of the manufacturer Ejendals AB. The object described is in conformity with Union harmonization legislation Personal Protective Equipment (PPE) Regulation EU 2016/425.

TEGERA® 48

High risk



Cat. III EN 420:2003
+ A1:2009



EN 388:2016
4102X



EN ISO 374-1:2016/Type A
AJKLOP



EN ISO 374-5:2016



REFERENCES TO HARMONIZED STANDARDS TO WHICH CONFORMITY IS DECLARED

EN 388:2016, EN 420:2003 + A1:2009, EN ISO 374-1:2016/Type A, EN ISO 374-5:2016 (VIRUS)

The article meets relevant requirements in European Regulation 1935/2004 (Materials in contact with food) and European Regulation 2023/2006 (GMP). The migration test performed according to EN 1186. The regulation 10/2011/EC excludes rubber material, instead reference to Bfr (Bundesinstitut für Risikobewertung) which clarifies test conditions 10 min, 40 °C for gloves.

IDENTIFICATION/NUMBER OF CERTIFICATION

2777/10719-3/E03-01

CERTIFICATION DATE

2020-02-27

CERTIFICATION EXPIRY DATE

2023-07-04

EU-TYPE EXAMINATION

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ONGOING CONFORMITY MODULE D, UNDER SURVEILLANCE OF THE NOTIFIED BODY

2777 Satra Technology Europe Ltd Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Leksand 2020-02-27

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