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ejendals

UKCA Declaration of Conformity

监 2777

This declaration of conformity is issued under the sole responsibility of the manufacturer Ejendals AB. The object described is in conformity with personal protective equipment (PPE) Regulation (EU) 2016/425 as amended and brought into UK law.

TEGERA® 849

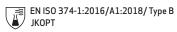
High risk



EN ISO 21420:2020



0 374-5:2016



フッ FDA co

FDA compliant material

REFERENCES TO DESIGNATED STANDARDS AND/OR TECHNICAL SPECIFICATIONS TO WHICH CONFORMITY IS DECLARED EN ISO 21420:2020, EN ISO 374-1:2016/A1:2018 Type B, 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 $10\,\mathrm{min}$, $40\,\mathrm{^{\circ}C}$ for gloves.

IDENTIFICATION/NUMBER OF CERTIFICATION

2777/10904-03/E03-01

CERTIFICATION DATE

2024-01-15

CERTIFICATION EXPIRY DATE

2028-08-21

EU-TYPE EXAMINATION

 $2777\,\mathsf{Satra}\,\mathsf{Technology}\,\mathsf{Europe}\,\mathsf{Ltd}\,\mathsf{Bracetown}\,\mathsf{Business}\,\mathsf{Park},\mathsf{Clonee},\mathsf{Dublin}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{Ireland}\,\mathsf{15},\mathsf{Dublin},\mathsf{$

ONGOING CONFORMITY MODULE C2, UNDER SURVEILLANCE OF THE NOTIFIED BODY

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Leksand 2024-01-15

Lena Prytz Supplier Quality Engineering Director Ejendals AB

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