



## UK DECLARATION OF CONFORMITY

*issued under the sole responsibility of the manufacturer listed below:*

### **Medical Devices Regulations 2002 Class I non-sterile, non-measuring devices PPE Regulation (EU) 2016/425 Category III Personal Protective Equipment**

**Manufacturer:** Palmero Healthcare  
120 Goodwin Place  
Stratford, CT USA

**Authorized Representative:** STERIS Solutions Limited  
Chancery House, Rayns Way  
Watermead Business Park, Syston  
Leicester  
LE7 1PF  
United Kingdom

**Product:** See attached table

**Classification:** Class I non-sterile, non-measuring according to Medical Devices Regulations 2002

Category III PPE as defined in Annex I of the EU Regulation 2016/425

We herewith declare that the above-mentioned product(s) meet the provisions of the Medical Devices Regulations 2002 (SI618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). The product has been subjected to conformity assessment procedures set out in the Medical Devices Regulations 2002.

We further declare that the above-mentioned product(s) meet the safety and performance requirements of the Personal Protective Equipment Regulation (EU) 2016/425 as amended and brought into UK law.

All supporting documentation is retained on the premises of the manufacturer.

**PPE Notified Body:** Shirley Technologies (Europe) Limited; #2895

**Core Materials Used:** Cost Cruncher Lead; Scatter Sentry Lead-Free – 0.35mm Pb Lead Equivalence

**Applied standards:** ISO 9001, ISO 14971, ISO 15223-1, ISO 13688, BS-EN 61331-1, BS-EN 61331-3

<b>ISO 9001 Certificate(s) #:</b>	CERT-0144026	<b>PPE Module B Certificate #</b>	SH01258
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<b>Start of UKCA marking:</b>	16 November 2022	<b>PPE Module D Certificate #</b>	SH01125
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**Place, Date of issue:** Stratford, CT 26 April 2024

### Technical Approval

**Signature:** *Stephen Testa*

Electronically signed by: Stephen Testa  
Reason: Approver  
Date: Apr 26, 2024 12:53 EDT

**Name and Title:** Stephen Testa, Sr. Manager QA

**Date:** 4/26/2024

### Regulatory Approval

**Signature:** 

Electronically signed by: Scott Philhower  
Reason: Approver  
Date: Apr 26, 2024 10:36 EDT

**Name and Title:** Scott Philhower, Sr. Manager RA

**Date:** 4/26/2024

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20AQUA-EU	PATIENT APRON AQUA EU	00840415104838
20UAQUA-EU	PATIENT APRON UNLEADED AQUA EU	00840415112680
20BEIGE-EU	PATIENT APRON BEIGE EU	00840415112161
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20GREY-EU	PATIENT APRON GREY EU	00840415112178
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27USMILEY-EU	CHILD'S PROTECTALL LEAD FREE SMILEY EU	00840415112352
27HAPPYFACE-EU	CHILD'S PROTECT APRON HAPPYFACE EU	00840415112628
27UHAPPYFACE-EU	CHILD'S PROTECTALL LEAD FREE HAPPYFACE EU	00840415113007