THIS ORIGINAL EQUIPMENT MANUFACTURER COMPLIANCE & DECLARATION POLICY

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Clause 1: Scope and Applicability

1.1 This Original Equipment Manufacturer (OEM) Compliance and Declaration Policy ("the Policy") governs all activities involving the design, manufacture, labelling, branding, or distribution of medical devices under Urathon Ltd's name in the United Kingdom.

1.2 It applies to all OEMs, virtual manufacturers, importers, distributors, and affiliates engaged in regulated product supply chains involving medical devices under UK jurisdiction.

1.3 While this Policy specifically applies to Continuous Glucose Monitoring (CGM) systems, it extends to any other Class I, IIa, IIb, or III medical devices placed on the UK market by or on behalf of Urathon Ltd.

Clause 2: Definitions

2.1 **Original Equipment Manufacturer (OEM)**: A legal entity responsible for the original design and manufacture of a medical device, which may be marketed under another name.

2.2 **Virtual Manufacturer**: A company that places its name on a device manufactured by a third party and assumes full regulatory liability under the **UK Medical Devices Regulations 2002**.

2.3 **UKCA Marking**: The conformity symbol required for medical devices sold in Great Britain, representing compliance with UK legislation.

2.4 **Declaration of Conformity (DoC)**: A legally binding document issued by the manufacturer confirming that the product satisfies all applicable regulatory and conformity assessment requirements under UK law.

Clause 3: UKCA Marking and Conformity

3.1 All medical devices marketed by or for Urathon Ltd must bear a valid **UKCA mark**, unless specifically exempt under transitional arrangements authorised by the **MHRA**.

3.2 Conformity assessments shall be conducted in accordance with device classification, using either self-certification or third-party approval via a **UK Approved Body** listed on the MHRA

registry.

3.3 The UKCA mark must appear on the product label, packaging, and instructions for use (IFU) in a **visible, legible, and indelible** manner, consistent with **Part II of UK MDR 2002**.

Clause 4: OEM and Virtual Manufacturer Obligations

4.1 Where Urathon Ltd acts as a virtual manufacturer, it shall bear all regulatory responsibilities including safety, performance, vigilance, and technical documentation.

4.2 A **legally binding agreement** must be in place between the OEM and the virtual manufacturer, stipulating:

- Roles and regulatory responsibilities
- Access rights to the OEM's complete technical file
- Timely update mechanisms for changes in product design or adverse events

4.3 The virtual manufacturer must keep a copy of the OEM's **technical documentation** on site and make it available to the **MHRA** or other authorities on request.

4.4 The OEM must promptly notify the virtual manufacturer of **material changes** to design, labelling, or performance, and cooperate with post-market surveillance activities.

Clause 5: Declaration of Conformity Requirements

5.1 No device shall be placed on the UK market without a complete and compliant **Declaration of Conformity (DoC)**.

5.2 The DoC must include:

- Name and address of the legal manufacturer or virtual manufacturer
- Precise product description, including model or catalogue number
- Applicable legislation (e.g. UK MDR 2002) and harmonised standards (e.g. ISO 13485, ISO 14971)
- Name and number of the UK Approved Body (if involved)
- Date of issue and authorised signatory's details
- Statement confirming conformity with all applicable regulations

5.3 The DoC must be maintained for **10 years** from the date of market placement and be **available in English**.

5.4 The DoC must be **available upon request** to the **MHRA**, NHS procurement entities, and any relevant enforcement authority.

5.5 In the event of **design changes, software updates, or clinical findings**, the DoC must be immediately reviewed and reissued.

Clause 6: Technical Documentation and Third-Party Assessment

6.1 The manufacturer must compile and maintain a **technical file** for each device, containing:

- Risk assessments (aligned with ISO 14971)
- Clinical evaluations (Annex XIV of MDR or UK equivalent)
- Design verification and validation records
- Product labelling and IFUs

6.2 If applicable, the Company may only engage **MHRA-listed UK Approved Bodies** for third-party conformity assessments.

6.3 Quality system documentation, including **ISO 13485 certification**, audit findings, and non-conformance records, must be retained and reviewed **at least annually**.

Clause 7: CGM System-Specific Requirements

7.1 CGM devices supplied or branded by Urathon Ltd must demonstrate:

- Continuous data stability across use durations
- Interference-resilience and user calibration accuracy
- Compliance with **IFCC glucose measurement standards**

7.2 All performance claims must be **evidenced through clinical evaluations**, design validations, and consistent post-market performance data.

7.3 Safety measures must ensure **cybersecurity**, **data protection (UK GDPR)**, and **fail-safe**

alerts for insulin-dependent users.

Clause 8: Post-Market Surveillance and Regulatory Reporting

8.1 The Company must implement a **Post-Market Surveillance (PMS) system** proportionate to the risk class and scale of the device's market deployment.

8.2 The PMS system must include:

- Vigilance reporting (per UK MDR Part IV)
- Complaint handling and root cause analysis
- Periodic Safety Update Reports (PSUR) for Class IIa and higher devices

8.3 PMS records shall be maintained and reviewed quarterly by the **Regulatory Affairs Officer** and escalated where material safety concerns arise.

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Annexure – 1 DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:
****Manufacturer Name**:** Urathon Ltd
****Manufacturer Address**:** Thane House, Hilmarton, Calne, SN118SB
****Product**:** Manual and Powered Mobility Aids (including Wheelchairs)
The object of the declaration described above is in conformity with the relevant statutory requirements:

- UK Medical Devices Regulations 2002 (as amended)
- Supply of Machinery (Safety) Regulations 2008
- Electrical Equipment (Safety) Regulations 2016, where applicable
- Electromagnetic Compatibility Regulations 2016, where applicable

Conformity assessment has been carried out in accordance with the following designated standards:

- ISO 7176 series (Wheelchair performance and safety)
- ISO 14971 (Risk management for medical devices)
- ISO 13485 (Quality management systems for medical devices)
- BS 8625 (Safety for transportable mobility aids)
- PAS 2012 (Accessible vehicle adaptation)

**Approved Body involved (if applicable) **: Name and ID of UK Approved Body
Additional Information: The technical documentation is maintained by the manufacturer and will be made available to the relevant authorities upon request.

Signed for and on behalf of Urathon Europe Ltd:

Name:
Position:
Place of Issue:
Date of Issue: 01/05/2025

Signature: _____