HEALTH AND SAFETY POLICY

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Clause 1: Scope and Applicability

1.1 This Health and Safety Policy ("the Policy") applies to all operations conducted by **Urathon Europe Ltd**, including the design, manufacture, testing, distribution, servicing, and use of medical devices, including wheelchairs and Continuous Glucose Monitoring (CGM) systems.

1.2 This Policy ensures compliance with statutory duties under the **Health and Safety at Work etc. Act 1974**, **UK Medical Devices Regulations 2002**, and the oversight of the **Medicines and Healthcare products Regulatory Agency (MHRA)**.

1.3 This Policy is binding on all employees, contractors, visitors, third-party service providers, and any individual operating on behalf of the Company.

Clause 2: Definitions

2.1 **MHRA**: The UK's competent authority for regulation and enforcement of medical devices and safety reporting under UK MDR.

2.2 **Post-Market Surveillance (PMS)**: The continuous, systematic collection and analysis of data relating to device safety and performance aftermarket release.

2.3 **Yellow Card Scheme**: The MHRA's official mechanism for reporting suspected adverse events involving medical devices.

Clause 3: Medical Devices Regulation and MHRA Compliance

3.1 All medical devices placed on the UK market must meet conformity assessment requirements under the **UK Medical Devices Regulations 2002**, including valid **UKCA** or **CE** marking as applicable.

3.2 All technical documentation (design dossiers, IFUs, labelling, risk assessments) shall be maintained in accordance with MHRA audit-readiness requirements and stored for a minimum of 10 years after the final unit is placed on the market.

Clause 4: Wheelchair Safety and Operations

4.1 **Product Safety and Instructions**: Each wheelchair must be accompanied by clear safety instructions, multilingual user guides, and accessible maintenance schedules.

4.2 **Vehicle Restraints (WTORS)**: Wheelchairs intended for transport must comply with **ISO 10542**, **BS 8625**, and **PAS 2012** safety standards.

4.3 **Transport Safety**: Securement systems, tie-downs, and occupant restraints must be tested and documented in line with **Regulations EC 2007/46** where relevant.

4.4 **Maintenance and Repairs**: Urathon shall provide customers with access to trained service technicians, OEM parts, and annual safety inspections.

4.5 **Training**: The Company shall offer user training, caregiver support, and distributor education for all wheelchair-related safety and handling.

4.6 **Adverse Events**: All wheelchair incidents must be reported internally and, where appropriate, to the MHRA under vigilance obligations.

Clause 5: CGM Safety and Quality Requirements

5.1 CGM systems must comply with UK MDR 2002, **NICE diabetes guidance**, and MHRA safety notices.

5.2 Devices must display appropriate CE/UKCA marks, validated through conformity assessments and testing by an Approved Body or Notified Body.

5.3 Sensors must undergo reliability testing across operational temperature, usage duration, and accuracy range thresholds.

5.4 Wireless data transmission must be secure, encrypted, and GDPR-compliant.

5.5 Hardware/software QMS procedures must align with **ISO 13485** and **IEC 62304** standards.

5.6 The Company shall promptly report CGM device issues under the MHRA's Yellow Card Scheme and retain records for audit.

5.7 All patient health data must be processed under **UK GDPR** and **Data Protection Act 2018**, including encrypted storage and strict role-based access.

5.8 PMS shall include trend analysis, complaint monitoring, and field safety corrective action planning.

5.9 Clinical investigations must follow **Good Clinical Practice (GCP)** and receive prior ethical approval.

Clause 6: Incident Reporting and Surveillance

6.1 Internal reporting protocols shall cover all adverse events, near-misses, malfunctions, and occupational incidents.

6.2 Any **reportable incidents under RIDDOR** (e.g. fatality, specified injury, disease) must be filed within statutory timeframes.

6.3 Safety data will feed into a central PMS system to inform design changes, root cause analysis, and audit findings.

6.4 Recall, corrective action, and communication logs must be documented in compliance with **UK MDR** and **FOIA 2000** where NHS contracts apply.

Clause 7: Monitoring, Training, and Review

7.1 All personnel shall undergo induction and periodic training covering health and safety law, role-specific risks, fire safety, COSHH, MHRA vigilance, and proper PPE use.

7.2 Annual health and safety audits will be conducted by a designated Competent Person as required under the **Management of Health and Safety at Work Regulations 1999**.

7.3 This Policy shall be reviewed every 12 months or after any significant incident, audit finding, or legal update.

Clause 8: Mental Health and Wellbeing *(New)*

8.1 The Company recognises mental health as a core component of workplace safety and wellbeing under the **Health and Safety Executive (HSE) Management Standards**.

8.2 Stress risk assessments will be conducted and reviewed regularly to support early intervention.

8.3 Access to mental health support, EAPs, and occupational health services shall be made available to all employees.

Clause 9: Contractor and Visitor Safety *(New)*

9.1 Contractors and visitors must comply with site-specific safety protocols and sign in/out in accordance with **Control of Contractors** procedures.

9.2 Risk assessments and method statements (RAMS) are required prior to commencement of any contractor activity on-site.

9.3 Emergency evacuation and hazard briefings must be provided to non-employees upon arrival.