


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

|  |   |  |
|--|---|--|
| <br><b>8400</b><br>Accredited to<br>ISO/IEC 17021-1: 2015<br>to provide management<br>systems certification | <b>TUV Rheinland UK Ltd</b>   |  |
|  | <b>Issue No: 005    Issue date: 18 December 2025</b>  |  |
|  | <b>3rd Floor, The Hub<br/>Blythe Valley Park<br/>Central Boulevard<br/>Shirley<br/>Solihull<br/>B90 8BG</b> | <b>Contact: Mr Lee Willison<br/>Tel: +44 (0)121 796 9400<br/>E-Mail: <a href="mailto:Lee.Willison@uk.tuv.com">Lee.Willison@uk.tuv.com</a><br/>Website: <a href="https://www.tuv.com/united-kingdom/en">https://www.tuv.com/united-kingdom/en</a></b> |

### SUMMARY OF ACCREDITED SCOPE

#### Product certification for

- **Pressure Equipment (Safety) Regulations 2016, SI 2016 No 1105 as amended**
- **Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended**

**Accredited to provide certification of the following Management Systems Standards and related Sector Schemes as detailed in this schedule:**

- **Medical Devices – Quality Management Systems (MD – QMS) to ISO 13485:2016**



**8400**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

## **Schedule of Accreditation**

issued by

### **United Kingdom Accreditation Service**

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005 **Issue date:** 18 December 2025

| KEY LOCATION ADDRESS  | MD-QMS |
|---|--------|
| 3rd Floor, The Hub<br>Blythe Valley Park<br>Central Boulevard<br>Shirley<br>Solihull<br>B90 8BG | ✓      |

This Certification Body has demonstrated to UKAS that it has the systems and processes in place to provide the competence and capability, including understanding of local requirements, to manage and issue accredited management systems certification in the country in which it is established and in any other country, for the standards and scopes detailed on this schedule, unless specifically detailed in the individual Management System scope table (*denoted by \**).



**8400**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

## **Schedule of Accreditation**

issued by

### **United Kingdom Accreditation Service**

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005 **Issue date:** 18 December 2025

#### **Accreditation for the purpose of UK Approved Body Activity in accordance with UKCA Requirements and UKAS Publication GEN 5**

| <b>Directive / Regulation</b>   | <b>Conformity Assessment procedure/ Module/article</b>  | <b>Category of products or individual products</b> | <b>Essential requirements: Product specification /Properties/Standards</b> | <b>Location code</b> |
|---|---|--|--|----------------------|
| <b>Pressure Equipment (Safety) Regulations 2016, SI 2016 No 1105 as amended</b> | <b>Conformity assessment procedures in accordance with Regulation 42 of the SI</b><br><br>Schedule 1A<br>Part 11 – Module H<br>Conformity based on full quality assurance | Category III Equipment                             | Schedule 2, assessment of technical documentation and quality system       |                      |



8400

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005 **Issue date:** 18 December 2025

#### Accreditation for the purpose of UK Approved Body Activity in accordance with UKCA Requirements and UKAS Publication GEN 5

| Directive / Regulation  | Conformity Assessment procedure/ Module/article | Category of products or individual products  | Essential requirements: Product specification /Properties/Standards | Location code |
|---|---|--|---|---------------|
| <b>Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended</b> | Schedule 11<br>Full quality assurance           | <p>The following equipment subject to noise limits Specified in <i>Schedule 1</i> and defined in <i>Schedule 4</i> of the regulations:</p> <ul style="list-style-type: none"> <li>• builders' hoists for the transport of goods (combustion-engine driven)</li> <li>• compaction machines (only vibrating and non-vibrating rollers, vibratory plates and vibratory rammers)</li> <li>• compressors (&lt;350 kW)</li> <li>• concrete-breakers and picks, hand-held</li> <li>• construction winches (combustion-engine driven)</li> <li>• dozers (&lt;500 kW)</li> <li>• dumpers (&lt;500 kW)</li> <li>• excavators, hydraulic or rope-operated (&lt;500 kW)</li> <li>• excavator-loaders (&lt;500 kW)</li> <li>• graders (&lt;500 kW)</li> <li>• hydraulic power packs</li> </ul> <p>landfill compactors, loader-type with bucket (&lt;500 kW)</p> | Assessment of quality system  |               |



8400

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No: 005   Issue date: 18 December 2025**

**Accreditation for the purpose of UK Approved Body Activity in accordance with UKCA Requirements and UKAS Publication GEN 5**

| Directive / Regulation   | Conformity Assessment procedure/ Module/article | Category of products or individual products   | Essential requirements: Product specification /Properties/Standards | Location code |
|--|---|---|---|---------------|
| <b>Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended (cont'd)</b> | Schedule 11<br>Full quality assurance (cont'd)  | <p>The following equipment subject to noise limits Specified in <i>Schedule 1</i> and defined in <i>Schedule 4</i> of the regulations: (cont'd)</p> <ul style="list-style-type: none"> <li>• lawnmowers (excluding agricultural and forestry equipment, and multi-purpose devices, the main motorised component of which has an installed power of more than 20 kW)</li> <li>• lawn trimmers/lawn edge trimmers</li> <li>• lift trucks, combustion-engine driven, counterbalanced (excluding "other counterbalanced lift trucks" as defined in Annex I, Item 36, second indent with a rated capacity of not more than 10tonnes)</li> <li>• loaders (&lt;500 kW)</li> <li>• mobile cranes</li> <li>• motor hoes (&lt;3 kW)</li> <li>• paver-finishers (excluding paver-finishers equipped with a high-compaction screed)</li> <li>• power generators (&lt;400 kW)</li> <li>• tower cranes</li> <li>• welding generators</li> </ul> | Assessment of quality system  |               |

END



**8400**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005    **Issue date:** 18 December 2025

## MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

In accordance with ISO/IEC 17021-1: 2015

### ISO 13485: 2016 Certification

| IAF Mandatory Scopes of Accreditation<br>Scope Reference | Technical Area  |
|--|---|
| <b>1.1 Non-active Medical Devices</b>                    | General non-active, non-implantable medical devices                 |
|  | Non-active implants   |
|  | Devices for wound care  |
|  | Non-active dental devices and accessories                           |
|  | Non-active medical devices other than specified above               |
| <b>1.2 Active Medical Devices (Non-Implantable)</b>      | General active medical devices                                      |
|  | Devices for imaging   |
|  | Monitoring devices  |
|  | Devices for radiation therapy and thermo therapy                    |
|  | Active (non-implantable) medical devices other than specified above |
|  |   |



**8400**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005    **Issue date:** 18 December 2025

**MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS**

In accordance with ISO/IEC 17021-1: 2015

**ISO 13485: 2016 Certification**

| IAF Mandatory Scopes of Accreditation<br>Scope Reference | Technical Area  |
|--|---|
| <b>1.4 In Vitro Diagnostic Medical Devices (IVD)</b>     | Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> <li>• Clinical Chemistry</li> <li>• Immunochemistry (immunology)</li> <li>• Haematology /Haemostasis /Immunohematology</li> <li>• Microbiology</li> <li>• Infection Immunology</li> <li>• Histology/cytology</li> <li>• Genetic Testing</li> </ul> |
|  | In vitro diagnostic instruments and software  |
|  | IVD medical devices other than specified above  |
| <b>1.5 Sterilisation Method for Medical Devices</b>      | Ethylene oxide gas sterilisation (EOG)  |
|  | Moist heat  |
|  | Aseptic processing  |
|  | Radiation sterilisation (e.g. gamma, x-ray, electron beam)  |
|  | Low temperature steam and formaldehyde sterilisation  |
|  | Thermic sterilisation with dry heat   |
|  | Sterilisation with hydrogen peroxide  |
|  | Sterilisation method other than specified above   |



**8400**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

## Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**TUV Rheinland UK Ltd**

**Issue No:** 005 **Issue date:** 18 December 2025

## MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

In accordance with ISO/IEC 17021-1: 2015

### ISO 13485: 2016 Certification

| IAF Mandatory Scopes of Accreditation<br>Scope Reference                    | Technical Area   |
|---|--|
| <b>1.6 Devices Incorporating/Utilising Specific Substances/Technologies</b> | Medical devices incorporating medicinal substances   |
|   | Medical devices utilising tissues of animal origin   |
|   | Medical devices incorporating derivatives of human blood   |
|   | Medical devices utilising micromechanics   |
|   | Medical devices utilising nanomaterials  |
|   | Medical devices utilising biological active coatings and/or materials being wholly or mainly absorbed            |
|   | Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above |
| END   |  |