

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.  
370 West 1700 South  
Logan  
Utah  
84321  
USA

Facility ID Number: F000174

Holds Certificate No:

**MDSAP 689350**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-03-28

Effective Date: 2022-01-11

Expiry Date: 2025-01-10



BSI Group America Inc. is an MDSAP authorized auditing organization

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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.  
370 West 1700 South  
Logan  
Utah  
84321  
USA

Holds Certificate No:

**FM 703046**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-12

Latest Revision Date: 2021-12-23

Effective Date: 2022-01-11

Expiry Date: 2025-01-10

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## **DECLARATION DE CONFORMITE CE**

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

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## **DECLARATION OF EC CONFORMITY**

*We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.*

*These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.*

*This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27<sup>th</sup>, 2023).*

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## **DECLARACIÓN CE DE CONFORMIDAD**

*Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.*

*Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.*

*Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).*

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Sées, le 29 juillet 2020

**Valérie LAMBERT,**

Responsable des Affaires Réglementaires

*Regulatory Affairs Manager*

*Responsable de los Asuntos Reglementarios*

**Cécile GOUBAULT,**

Directeur Général Délégué

*Managing Director*

*Directora General*

| REACTIFS - REAGENTS - REACTIVOS                                 | RÉFÉRENCES - REFERENCES - REFERENCIAS   | Code GMDN   |
|-----------------------------------------------------------------|-----------------------------------------|-------------|
| Metabolites divers / Miscellaneous metabolites                  |                                         |             |
| ALBUMIN                                                         | ALBU-0600/0700/0250                     | 53597       |
| ALBUMIN ENVOY                                                   | ALBU-0850                               |             |
| BILIRUBIN DIRECT 4+1                                            | BIDI-0600/0250                          | 53233       |
| BILIRUBIN TOTAL 4+1                                             | BITO-0600/0250                          | 53229       |
| BILIRUBIN TOTAL & DIRECT 4+1                                    | BITD-0600                               | 53229/53233 |
| CREATININE ENVOY                                                | CRSL-0850                               | 53250       |
| CREATININE JAFFE                                                | CRCO-0600/0700                          | 53251       |
| CREATININE PAP SL                                               | CRSL-0630/0250                          | 53250       |
| DIRECT BILIRUBIN ENVOY                                          | BIDV-0850                               | 53233       |
| GLUCOSE ENVOY                                                   | GPST-0850                               | 53301       |
| GLUCOSE HK SL                                                   | GHSL-0600/0250                          |             |
| GLUCOSE PAP SL                                                  | GPST-0507/0500/0707/0700/0250/0455/0497 | 53342       |
| LACTATE                                                         | LACT-0100                               |             |
| MICROPROTEIN PLUS                                               | PRTU-0600/0250                          | 53481       |
| PHOSPHORUS                                                      | PHOS-0600/0230                          | 59123       |
| PHOSPHORUS ENVOY                                                | PHOS-0850                               |             |
| TOTAL BILIRUBIN ENVOY                                           | BITV-0850                               | 53229       |
| TOTAL PROTEIN ENVOY                                             | PROB-0850                               | 53985       |
| TOTAL PROTEIN PLUS                                              | PROB-0600/0700/0250                     |             |
| UREA ENVOY                                                      | URSL-0850                               | 53587       |
| UREA UV SL                                                      | URSL-0407/04270420/0500/0507/0250/0455  |             |
| URIC ACID ENVOY                                                 | AUVD-0850                               | 53583       |
| URIC ACID MONO SL                                               | AUML-0497/0427/0420/0500/0507/0707/0250 |             |
| URIC ACID SL                                                    | AUSL-0250                               |             |
| Enzymes / Enzymes                                               |                                         |             |
| ALP (DEA) SL                                                    | PASL-0400/0420/0230                     | 52928       |
| ALP ENVOY                                                       | PIVD-0850                               |             |
| ALP IFCC                                                        | ALPI-0230                               | 52923       |
| ALT ENVOY                                                       | ALSL-0850                               |             |
| ALT/GPT 4+1 SL                                                  | ALSL-0410/0430/0510/0250/0455           | 52940       |
| AMYLASE ENVOY                                                   | AMSL-0850                               |             |
| AMYLASE SL                                                      | AMSL-0390/0400/0230                     | 52954       |
| AST ENVOY                                                       | ASVD-0850                               |             |
| AST/GOT 4+1 SL                                                  | ASSL-0410/0430/0510/0250/0455           | 52971       |
| CHOLINESTERASE                                                  | CHES-0053                               |             |
| CK ENVOY                                                        | CKSL-0850                               | 53003       |
| CK-MB ENVOY                                                     | CMSL-0850                               | 52994       |
| CK-MB SL                                                        | CMSL-0410/0430/0230                     |             |
| CK NAC SL                                                       | CKSL-0410/0430/0230                     | 53003       |
| GAMMA-GT PLUS SL                                                | GISL-0400/0420/0250                     | 53027       |
| GGT ENVOY                                                       | GISL-0850                               |             |
| LDH ENVOY                                                       | LLSL-0850                               | 53072       |
| LDH-L SL                                                        | LLSL-0400/0420/0230                     |             |
| LIPASE ENVOY                                                    | LPST-0850                               | 53108       |
| LIPASE SL                                                       | LPST-0230                               |             |
| Electrolytes - Oligo-éléments / Electrolytes - Trace-elements   |                                         |             |
| CALCIUM ARSENAZO                                                | CALA-0600/0250                          | 45789       |
| CALCIUM ENVOY                                                   | CALA-0850                               |             |
| CHLORIDE                                                        | CHLO-0600/0250                          | 60037       |
| IRON ENVOY                                                      | FEFE-0850                               | 54758       |
| IRON FERENE                                                     | FEFE-0230/0600                          |             |
| MAGNESIUM ENVOY                                                 | MAGX-0850                               | 46795       |
| MAGNESIUM XB                                                    | MGXB-0250/0600                          |             |
| MAGNESIUM XYLIDYL                                               | MAGX-0230/0600                          |             |
| Lipides / Lipids                                                |                                         |             |
| CHOLESTEROL ENVOY                                               | CHSL-0850                               | 53359       |
| CHOLESTEROL SL                                                  | CHSL-0507/0500/0700/0707/0250/0455/0497 |             |
| CHOLESTEROL HDL SL 2G                                           | HDLL-0230/0380/0390                     | 53391       |
| CHOLESTEROL LDL SL 2G                                           | LDLL-0230/0380/0390                     | 53395       |
| HDL CHOLESTEROL                                                 | CHDL-0250/0600                          | 53391       |
| HDL CHOLESTEROL ENVOY                                           | HDLL-0850                               |             |
| LDL CHOLESTEROL                                                 | CLDL-0250                               | 53395       |
| LDL CHOLESTEROL ENVOY                                           | LDLL-0850                               |             |
| TRIGLYCERIDES ENVOY                                             | TGML-0850                               | 53460       |
| TRIGLYCERIDES MONO SL NEW                                       | TGML-0427/0425/0515/0700/0517/0707/0497 |             |
| TRIGLYCERIDES SL                                                | TGML-0250/0455                          |             |
| Contrôles-Calibrants-Standards / Controls-Calibrators-Standards |                                         |             |
| CHOLESTEROL HDL 2G CALIBRATOR                                   | HDLL-0011/0041                          | 44696       |
| CHOLESTEROL LDL 2G CALIBRATOR                                   | LDLL-0011/0041                          | 41728       |
| CHOLESTEROL Standard 200 mg/dL                                  | CHOL-0055                               | 44698       |
| CK-MB CONTROL                                                   | CKMB-0900                               | 44693       |
| ELICAL 2                                                        | CALI-0550                               | 47868       |
| ELITROL I                                                       | CONT-0060                               | 47869       |
| ELITROL II                                                      | CONT-0160                               |             |
| GLUCOSE Standard 100 mg/dL                                      | GLUP-0055                               | 41818       |
| HDL LDL CALIBRATOR                                              | HLCA-0041                               | 47868       |
| ISE CONTROL I                                                   | ISCT-0046                               | 47869       |
| ISE CONTROL II                                                  | ISCT-0047                               |             |
| MICROPROTEIN PLUS Standard 100 mg/dL                            | PRTU-0022                               | 53482       |
| TRIGLYCERIDES Standard 200 mg/dL                                | TRIG-0055                               | 44702       |
| UREA Standard 50 mg/dL                                          | URUV-0055                               | 53588       |
| URIC ACID Standard 6 mg/dL                                      | ACUR-0055                               | 44704       |

| REACTIFS - REAGENTS - REACTIVOS                                                                                                   | RÉFÉRENCES - REFERENCES - REFERENCIAS | Code GMDN |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-----------|
| Protéines spécifiques / Specific proteins                                                                                         |                                       |           |
| ANTI-STREPTOLYSIN O                                                                                                               | ASLO-0250                             | 59055     |
| CRP IP                                                                                                                            | ICRP-0400                             | 53705     |
| CRP IP CALIBRATOR SET                                                                                                             | ICRP-0043                             | 41838     |
| CRP IP CONTROL I                                                                                                                  | ICRP-0046                             | 41839     |
| CRP IP CONTROL II                                                                                                                 | ICRP-0047                             |           |
| CRP WR                                                                                                                            | CRPW-0230                             | 53705     |
| CRP WR CALIBRATOR SET                                                                                                             | CRPW-0043                             | 41838     |
| CRP WR CONTROL                                                                                                                    | CRPW-0045                             | 41839     |
| CRP WR ENVOY                                                                                                                      | CRPW-0850                             | 53705     |
| FERRITIN                                                                                                                          | IFRT-0230                             | 53718     |
| FERRITIN CALIBRATOR                                                                                                               | IFRT-0042                             | 41927     |
| HAPTOGLOBIN IP                                                                                                                    | IHAP-0400                             | 53737     |
| HbA1c                                                                                                                             | HBAC-0240                             | 59090     |
| HbA1c CALIBRATOR SET                                                                                                              | HBAC-0043                             | 53315     |
| HbA1c CONTROL L + H                                                                                                               | HBAC-0049                             | 44435     |
| IgA IP                                                                                                                            | IIGA-0400                             | 53760     |
| IgG IP                                                                                                                            | IIGG-0400                             | 53787     |
| IgM IP                                                                                                                            | IIGM-0400                             | 53795     |
| μALBUMIN IP                                                                                                                       | IMAL-0400                             | 53475     |
| μALBUMIN IP CALIBRATOR SET                                                                                                        | IMAL-0043                             | 53477     |
| μALBUMIN IP CONTROL I                                                                                                             | IMAL-0046                             | 53478     |
| μALBUMIN IP CONTROL II                                                                                                            | IMAL-0047                             |           |
| OROSOMUCOID IP                                                                                                                    | IORO-0400                             | 53606     |
| PREALBUMIN IP                                                                                                                     | IPAL-0400                             | 53957     |
| PROTEIN IP CALIBRATOR SET                                                                                                         | IPRO-0043                             | 53593     |
| RF CALIBRATOR                                                                                                                     | IRFA-0042                             | 42230     |
| RHEUMATOID FACTOR                                                                                                                 | IRFA-0230                             | 55111     |
| RHEUMATOLOGY CONTROL I                                                                                                            | IRCT-0046                             | 47869     |
| RHEUMATOLOGY CONTROL II                                                                                                           | IRCT-0047                             |           |
| TRANSFERRIN IP                                                                                                                    | ITRF-0400                             | 59041     |
| Vitamines/Vitamins                                                                                                                |                                       |           |
| VITAMIN D                                                                                                                         | VITD-0250                             | 54476     |
| VITAMIN D CALIBRATOR SET                                                                                                          | VITD-0043                             | 54474     |
| VITAMIN D CONTROL SET                                                                                                             | VITD-0049                             | 54475     |
| ISE Solutions pour électrodes selectives d'ions /<br>ISE Solutions for ion-selective electrodes                                   |                                       |           |
| ISE BASELINE SOLUTION ENVOY                                                                                                       | ISBA-0850                             | 59238     |
| ISE CALIBRATORS                                                                                                                   | ISCA-0250                             | 52867     |
| ISE CALIBRATOR ENVOY                                                                                                              | ISCV-0850                             |           |
| ISE CLEANER/CONDITIONER                                                                                                           | ISCC-0280                             | 59058     |
| ISE DILUENT                                                                                                                       | ISDI-0250                             | 58237     |
| ISE DILUENT ENVOY                                                                                                                 | ISDV-0850                             |           |
| ISE REFERENCE SOLUTION                                                                                                            | ISRS-0800                             | 59238     |
| ISE REFERENCE SOLUTION ENVOY                                                                                                      | ISRS-0850                             |           |
| Solutions de lavage pour les équipements ELITech Clinical Systems /<br>Cleaning solutions for ELITech Clinical Systems Equipments |                                       |           |
| ACID SOLUTION for ELITech Clinical Systems Analyzers                                                                              | SLHC-5900                             | 59058     |
| SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers                                                                   | SLNA-5900                             | 59058     |
| SYSTEM SOLUTION                                                                                                                   | SLSY-5905                             | 58236     |
| SYSTEM SOLUTION for ELITech Clinical Systems Analyzers                                                                            | SLSY-5900                             |           |
| Tests d'agglutination / Agglutination tests                                                                                       |                                       |           |
| CRP LATEX                                                                                                                         | LXCR-0112                             | 53707     |

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info.ecsnl@elitechgroup.com  
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Chamber of Commerce 09175642

To: Whom it May Concern

**Regulatory status of parts & accessories**

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.



Adriaan P. Intveld  
Manager Quality Assurance & Regulatory Affairs

| Part number | Description                  | IVD medical device | IVD accessory | general laboratory use | spare part | supporting part |
|-------------|------------------------------|--------------------|---------------|------------------------|------------|-----------------|
| 1540-001    | Anti-Slip sheet              |                    |               |                        |            | ✓               |
| 2206-007    | Cooling Liquid (1 L)         |                    |               |                        |            | ✓               |
| 3062-021    | Sample cup (1000 pcs)        |                    | ✓             |                        |            |                 |
| 3062-033    | Sample tube 6 ml (500 pcs)   |                    |               |                        |            | ✓               |
| 3062-040    | Water container 10 L         |                    |               |                        |            | ✓               |
| 3062-041    | Water container 5 L          |                    |               |                        |            | ✓               |
| 3066-155    | Syringe 100 µl               |                    | ✓             |                        |            |                 |
| 3066-156    | Syringe 1 ml                 |                    | ✓             |                        |            |                 |
| 3069-040    | Keyboard Dust cover          |                    |               |                        |            | ✓               |
| 3069-047    | Keyboard Dust cover          |                    |               |                        |            | ✓               |
| 3070-518    | Cap holder                   |                    |               |                        |            | ✓               |
| 3070-538    | Cap rotor Left               |                    |               |                        |            | ✓               |
| 3070-539    | Cap rotor right              |                    |               |                        |            | ✓               |
| 3201-002    | Dichromate 8 Abs (25ml)      |                    | ✓             |                        |            |                 |
| 3365-192    | USB Stick                    |                    |               |                        |            | ✓               |
| 3374-003    | Mains cable (USA)            |                    |               |                        |            | ✓               |
| 3374-059    | Pumpunit cable               |                    | ✓             |                        |            |                 |
| 3374-066    | Mains cable                  |                    |               |                        |            | ✓               |
| 3374-097    | Serial Null-modem cable      |                    |               |                        |            | ✓               |
| 3374-286    | USB Extension cable          |                    |               |                        |            | ✓               |
| 4804-038    | Reagent identification Disc  |                    |               |                        |            | ✓               |
| 6001-826    | Diluted Waste container      |                    | ✓             |                        |            |                 |
| 6001-827    | Concentrated Waste container |                    | ✓             |                        |            |                 |
| 6001-860    | Water container              |                    | ✓             |                        |            |                 |
| 6001-861    | Tube assy (analyser)         |                    | ✓             |                        |            |                 |
| 6001-872    | Tube assy (cooling unit)     |                    | ✓             |                        |            |                 |
| 6002-102    | Assorter unit                |                    |               |                        | ✓          |                 |
| 6002-386    | System software on CD        |                    | ✓             |                        |            |                 |
| 6002-706    | Reaction Rotor set (3 pcs)   |                    | ✓             |                        |            |                 |
| 6002-726    | System Disc                  |                    | ✓             |                        |            |                 |
| 6002-817    | Bottle 30 ml (20 pcs)        |                    | ✓             |                        |            |                 |
| 6002-818    | Bottle 15 ml (20 pcs)        |                    | ✓             |                        |            |                 |
| 6002-904    | Water container 5 L          |                    | ✓             |                        |            |                 |
| 6002-910    | Assorter unit                |                    |               |                        | ✓          |                 |
| 6002-913    | External tubing              |                    | ✓             |                        |            |                 |
| 6003-074    | System software on USB stick |                    | ✓             |                        |            |                 |
| 6003-444    | Diluted Waste Container 5 L  |                    | ✓             |                        |            |                 |
| 6003-466    | Keyboard Support option      |                    |               |                        |            | ✓               |
| 6003-797    | CW Waste Container 2 L       |                    | ✓             |                        |            |                 |
| 6003-808    | Assorter unit                |                    |               |                        | ✓          |                 |

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Queensway South  
Team Valley Trading Estate  
Gateshead  
Tyne and Wear  
NE11 0SD  
United Kingdom

Holds Certificate Number:

**MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

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Certificate No: **MD 69326**

| Location                                                                                                                                                                          | Registered Activities                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Helena Laboratories (UK) Ltd<br>trading as Helena Biosciences Europe<br>Sunderland Enterprise Park<br>Colima Avenue<br>Sunderland<br>SR5 3XB<br>United Kingdom                    | The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables. |
| Helena Laboratories (UK) Ltd<br>trading as Helena Biosciences Europe<br>Queensway South<br>Team Valley Trading Estate<br>Gateshead<br>Tyne and Wear<br>NE11 0SD<br>United Kingdom | The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables. |



Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.