Creation Date : 10/04/2021

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| National Standards Authority of Ireland (NSAI)<br>1 Swift Square, Northwood, Santry<br>Dublin 9<br>Ireland | 0050 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |
| | | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |
| | | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | limited to cardiac assist & circulatory support devices |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7003 - Medical devices incorporating derivates of human blood according to Directive 2000/70/EC, | | | |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | amended by Directive 2001/104/EC | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.<br>Via Quintiliano, 43<br>20138 - MILANO<br>Italy | 0051 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| TÜV SÜD Product Service GmbH | 0123 | *AIMD 0100 - General active implantable medical | EC declaration of | Annex 2 | |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| Zertifizierstellen<br>Ridlerstraße 65<br>80339 MÜNCHEN<br>Germany | | devices<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 5<br>Annex 3<br>Annex 4 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7003 - Medical devices incorporating derivates of human blood according to Directive 2000/70/EC, amended by Directive 2001/104/EC | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation with liquid |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | | | | sterilants |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| TÜV Rheinland LGA Products GmbH<br>Tillystraße 2<br>90431 Nürnberg<br>Germany | 0197 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | products for stimulation only, excluding brain stimulation and cardiac pacemakers |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, electron beam), low temperature steam and formaldehyde |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | | | | sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| DEKRA Certification B.V.<br>Meander 1051 / P.O. Box 5185<br>6825 MJ ARNHEM / 6802 ED ARNHEM<br>Netherlands | 0344 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7003 - Medical devices incorporating derivates of human blood according to Directive 2000/70/EC, | | | |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | amended by Directive 2001/104/EC | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| GMED<br>1, rue Gaston Boissier<br>75015 PARIS<br>France | 0459 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | *MDS 7006 - Medical devices in sterile condition | | | Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) and non-typical methods (chemical sterilisation, dry heat sterilisation, Hydrogen peroxid with or without plasma process sterilisation, Ultra High Temperature Infusion sterilisation process). |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH<br>Pilatuspool 2<br>20355 HAMBURG<br>Germany | 0482 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination | Annex 2<br>Annex 5<br>Annex 3 | nonactive accessories to active implantable medical devices |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat |
| POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.<br>ul. Pu#awska 469<br>02-844 Warszawa<br>Poland | 1434 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7003 - Medical devices incorporating derivates of | | | |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | human blood according to Directive 2000/70/EC, amended by Directive 2001/104/EC | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |
| CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft.<br>Erd# u.101.<br>Budakeszi<br>Hungary | 2409 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | regarding Annex 2 or 5 |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | regarding Annex 2 or 5 |
| | | *MDS 7006 - Medical devices in sterile condition | | | regarding Annex 2 or 5 Including aseptic processing, ethylene oxide gas sterilisation (EOG), radiation sterilization (gamma,x-ray, electron beam), moist heat sterilization |

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd | | | regarding Annex 2 or 5 |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | regarding Annex 2 or 5 |
| BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP Amsterdam<br>Netherlands | 2797 | *AIMD 0100 - General active implantable medical devices<br>- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition<br>- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances<br>- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |
| | | *MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC | | | |
| | | *MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013) | | | |
| | | *MDS 7003 - Medical devices incorporating derivates of human blood according to Directive 2000/70/EC, amended by Directive 2001/104/EC | | | |
| | | *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | | | |
| | | *MDS 7006 - Medical devices in sterile condition | | | |
| | | *MDS 7007 - Medical devices utilising micromechanics | | | |
| | | *MDS 7008 - Medical devices utilising nanomaterials | | | |
| | | *MDS 7009 - Medical devices utilising biological active | | | |

## LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 90/385/EEC Active implantable medical devices

| Name and address of the notified bodies | ID | Responsible for the following products /Horizontal technical competence | Responsible for the following procedures or modules | Annexes or articles of the directives | Limitations (English only) |
|---|---|---|---|---|---|
| | | coatings and/or materials or being wholly or mainly absorbd | | | |
| | | *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | | | |