

## APPENDIX A

In line with Commission guidance the UK Competent Authority consider the following are not medical devices under the **Medical Devices Directives (MDD) 93/42/EEC**, and will not require notification to the UK Competent Authority responsible for the Directive, unless a medical claim is being made by the manufacturer for the device, which must then be stated in the instructions for use. This is a list of examples only and is not exhaustive.

### TOILETRY AND COSMETICS PRODUCTS, EXAMPLES:

- Tooth Brushes, Dental Sticks, Dental Floss, Un-Medicated Dental Chewing Gums
- Baby Nappies, Hygiene Tampons, Mattress Protectors
- Contact Lenses Without Corrective Function Intended to Provide Colour to the Eyes (Please Note: Contact Lenses with corrective function, are classified as a Class IIa medical device)
- Instruments for Tattooing
- Deodorants for Use With Devices
- Wigs
- Hand Cleansing Wipes considered to be a cosmetic product.

### PERSONAL PROTECTIVE EQUIPMENT, EXAMPLES:

- Self Rescue Apparatus
- Mouth-Guards
- Ionising Radiation Protective Clothing
- Eye Protecting Visors
- Protective Gloves (e.g. for use in a Medical Laboratory)

### DISINFECTANTS:

- Wipes/Swabs, brushes etc used to disinfect the skin of patients are usually regulated as medicinal products, and would be regulated by our Medicines Division of the MHRA.

- Wipe/Swaps/Brushes used by healthcare professionals to disinfect themselves (or other items not classified as medical devices), are usually regulated as Biocides, and enforced by the Health and Safety Executive.

#### **OTHER EQUIPMENT, EXAMPLES**

- Acoustic Signals at Traffic Lights
- Breathalysers, other Blood or Air Alcohol Measuring Devices
- Non Sterile Home, Occupational, Recreational Protective/Safety Apparel
- Non Prescription Sunglasses
- Consumer Products Aimed at Comfort
- Products for Sport or Leisure
- Surgical Training Kits/Packs (kits/packs used for training only)

## APPENDIX B

### Article 14 of the MDD 93/42EC: REGISTRATION OF PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE MARKET

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**Note:** If you are unable to assign an appropriate product code for a device and you wish to register with the UK Competent Authority, please enter a brief description of the device(s), its intended use, and mode of action in **Section 7a, 8a, or 9a** of the registration form RG2. It may also help us, if a picture or technical diagram of the device is also provided, in addition to the completed registration form.



## CLASS I DEVICES

Please note this list is for guidance only and there are likely to be many more Class I Devices than just those listed here.

If you cannot find an appropriate category and code for a device needing to be notified please enter a brief description, and what is the intended use in of the device(s), in **section 7a** of the RG2 form.

The inclusion of a device category on this list is not a statement that it necessarily falls within Class I. The risk classification of a product will vary dependant upon the claims made for it, and the materials it contains. Manufacturers should review the classification of their products on a case by case basis in accordance with the Rules set out in **Annex IX of the MDD 93/42EEC**.

### Administration

- A 1** Measuring and mixing devices for medicines
- A 2** Inhalation Devices (e.g. Chamber Spacers)
- A 3** Sets - Solution/Irrigation (Gravity Only)
- A 4** Syringes (Hypodermic/Oral/Irrigation)
- A 5** Dispensers (Cement, etc.) and Accessories
- A 6** Sensitivity Testing Devices
- A 7** Non-Active Auto injector Devices
- A 8** Non-Active Infusion Devices and Accessories

### Dental

- B 1** Dental Lights
- B 2** Dental Diagnostic Fibre Optic Hand pieces
- B 3** Dental Instruments (Reusable and Non-Powered)
- B 4** Dental Prophylaxis Paste (Non-Fluoride)
- B 5** Handheld Dental Mirrors and Accessories

- B 6** Impression Materials, Trays and Adhesives / Bite Wafers
- B 7** Orthodontic Materials (Extra-Oral/Intra-Oral Transient and Short-Term Use)
- B 8** Retraction Cords/Dental Wedges/Rubber Dam/Matrix Bands
- B 9** Articulating Paper/Spray
- B 10** Waxes
- B 11** Dental Unit Accessories
- B 12** Artificial Teeth
- B 13** Base Materials
- B 14** Dental Mouth Wash Tablets (Non-Medicated)
- B 15** Denture Lining Materials/Adhesives
- Z 169** Denture Cleaning Liquids/Tablets (Non-Disinfecting)(Dental Devices)
- Z 195** Dental Brace/Denture Fitting Aid(Dental Devices)
- Z 275** Denture Cleaning Brushes(Dental Devices)

#### **Diagnostic**

- C 1** Conductive Gels
- C 2** Electrodes/Transducers and Accessories
- C 3** Peak Flow Meters
- C 4** Sphygmomanometers and Accessories
- C 5** Stethoscopes
- C 6** Thermometers (Clinical)
- C 7** Examination/Procedure Gloves
- C 8** Blood Sampling Devices (Re-Usable)
- C 9** Endoscopes/Endoscopic Instruments and Accessories
- C 10** Image Storage and Retrieval System
- C 11** Laryngoscopes/Otoscopes and Accessories
- C 12** X-Ray Cassettes, Cassette Holders, Image Enhancers and Intensifying Screens
- C 13** Radiographic Film Processing Chemicals
- C 14** X-Ray Film Illuminators
- C 15** Sampling and Cell Collection Devices (Patient Contact - not IVDs)
- Z 102** Audiometer Accessories(Electro-Medical Mechanical Devices)
- Z 202** X-Ray Film Markers and Accessories(Diagnostic and Therapeutic Radiation Devices)



**Z 203** Patient Radiation Protection Products and Accessories(Diagnostic and Therapeutic Radiation Devices)

**Dressings**

- D 1** Bandages (e.g. Support/Tubular/Adhesive/Plaster of Paris/Cast Liners/Resin)
- D 2** Cotton Wool/Gauze/Non Woven(Ribbons/Swab/Buds)
- D 3** Adhesive Plasters/Dressings/Tapes/Barrier Films
- D 4** Eye Occlusion Plasters/Shields and Corneal Shields
- D 5** Chiropody Dressings and Pads
- O 8** Wound Manager(Single Use)
- Z 149** Dressing Adhesive Removers(Single Use)

**Equipment and Furnishings**

- E 1** Allergen Resistant Bedding
- E 2** Examination/Treatment Couches and Leg/Arm Rests
- E 3** Hospital Beds and Patient Positioning Aids
- E 4** Patient Hoists/ Transfer Aids and Accessories
- E 5** Pressure Relief Devices and Accessories
- E 6** Treatment Chairs (Chiropody/Dental/Ophthalmic)
- E 7** Stretchers/Chairs/Hospital Trolleys (Patient Transport)
- E 8** Traction and Surgical Immobilisation Devices
- E 9** Medical Examination Luminaries
- E 10** Rehabilitation Equipment
- E 11** Splints (Limb/Body/Ear) / Collars
- E 12** Resuscitation Devices (Non-Active) and Accessories
- E 13** Warming and Cooling Pads and Blankets (Non-Active and Non-Chemical)
- O 7** Speech / Breathing Training Devices(Technical Aids for Disabled Persons)
- Z 50** Cleaner/ Washer for Medical Devices(Hospital Hardware)
- Z 125** Ultrasonic Cleaners And Solutions(Hospital Hardware)
- Z 131** Surgical Equipment Sterile Drapes(Hospital Hardware)
- Z 135** Autoclave Accessories (e.g. Trays And Tray Lifters, Shelves, Racks)(Hospital Hardware)
- Z 143** Speech Synthesisers/Communication Aids/Voice Amplification Systems(Technical Aids for Disabled Persons)

- Z 154** Tourniquets and Tourniquet Machines (Electro-Medical Mechanical Devices)(can use code O7 - Technical Aids for Disabled Persons pg 7)
- Z 170** Instrument Cleaning Solutions/Wipes (Non-Disinfecting)(Hospital Hardware)

### **Ophthalmic**

- F 1** Lamps (Ophthalmic Examination)
- F 2** Fundas Cameras/Keratometers/Slit Lamp Microscopes and Associated Software
- F 3** Low Vision Aids
- F 4** Operating Room Microscopes/Magnification Systems
- F 5** Ophthalmoscopes/ Retinasopes
- F 6** Spectacle Lenses
- F 7** Spectacle Frames
- F 8** Ready-Made Spectacles (Non-Prescribed)
- F 9** Sight Testing Devices
- O 9** Schirmer Tear Test (Sterile Product) (Ophthalmic and Optical Devices)
- Z 45** Class I Tonometer(Reusable)
- Z 105** Eye Speculums(Ophthalmic and Optical Devices)
- Z130** Contact Lens accessories(Ophthalmic and Optical Devices)
- Z 148** Eye Baths/Irrigation Systems And Eyewash Solutions(Ophthalmic and Optical Devices)

### **Orthoses and Prostheses**

- G 1** Orthopaedic Footwear
- G 2** Orthoses (Lower and Upper Limb/Spinal/Abdominal/Neck/Head)
- G 3** Trusses
- G 4** Compression Hosiery/Garments
- G 5** External Limb Prostheses and Accessories
- G 6** Stump Socks and Boards
- G 7** Orthopaedic Casting/Support Products and Accessories
- Z 176** Postural Support Products(Technical Aids for Disabled Persons)

## **Surgical**

- H 1      Umbilical Clamps/Tape
- H 2      Tubes (Oesophageal/Rectal) and Accessories
- H 3      Enema and Douche Devices
- H 4      Incision Drapes/Theatre Clothing
- H 5      Surgical Instruments (Reusable and Non-Powered)
- H 6      Pre-Operative Devices (Razor/Marker Pen)
- H 7      Airway Devices/Monitoring Equipment and Accessories
- H 8      Non-Invasive Drainage Devices and Accessories
- H 9      Surgical Instrument Accessories
- H 10     Sterilisation Packaging
- H 11     Accessories For Implantable Devices (Non-Invasive)
- H 12     Operating Tables and Accessories
- Z 116    Vaginal Speculums(Reusable Devices)
- Z 136    Electrosurgical Accessories(e.g. Transient Invasive Electrodes, Footswitches)  
(Electro-Medical Mechanical Devices)

## **Walking Aids and Wheelchairs**

- I 1      Crutch/Walking Stick
- I 2      Walking Frame/Multi-Leg Walking Aid/Standing Frame
- I 3      Rollator/ Mobilator
- I 4      Wheelchairs (Non-Powered) and Accessories
- I 5      Wheelchairs (Powered) and Accessories
- I 6      Mobility Aids for the Visually Impaired
- Z168    Rehabilitation Tricycles/Mobility Carts(Technical Aids for Disabled Persons)

## **Waste Collection**

- J 1      Ostomy Collection Devices and Accessories
- J 2      Incontinence Pads and Accessories
- J 3      Urinary Bags and Accessories
- J 4      Non-Invasive Tubing (Waste Disposal)
- J 5      Penile Sheaths



## J 6 Urinary Catheters (Transient Use) and Accessories

### Other

- Z 48** Telemedicine Accessories(Reusable)
- Z 129** Acupressure Devices
- Z 146** Head Lice Devices(Reusable)
- Z 147** Dilators And Lubricants(Reusable)
- Z 162** Nasal Speculum(Reusable)
- Z 218** Lubricants (instruments/electrode pads)(Single Use)