

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

CONTENTS

CLASS I	PAGES	3 – 7
Administration, and Dental	Pg	3
Diagnostic, Dressing, and Equipment and Furnishings	Pg's	4 – 5
Ophthalmic, Orthoses and Prostheses, and Surgical	Pg	5 - 6
Walking Aid and Wheelchairs, Waste Collection and Other	Pg	6
CUSTOM MADE DEVICES	PAGE	7
SYSTEM AND PROCEDURE PACKS (ARTICLE 12)	PAGE	8

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/ Retinascopes
- 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)

CUSTOM MADE DEVICES

Please note that the following products will only be considered as custom-made if they are manufactured in accordance with a professional's written prescription for the sole use of a particular patient and are not adapted from mass produced items. Some of the products listed below will also be available as standard (i.e. non-custom-made) and such products must be notified in their own right. The following products are listed for guidance only and there are likely to be many more custom made 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 of device(s), and what is the intended use of the device(s), in **section 8a** of form RG2.

- K 1** Dental Appliances/Prostheses
- K 2** Hearing Aid Inserts
- K 3** Prescribed Orthopaedic Footwear
- K 4** Artificial Eyes
- K 5** Orthoses and Prostheses - External (Made Direct from Casts/Prescriptions)
- K 6** Orthopaedic Implants
- K 7**
Maxillo-Facial Devices
- K 8** Standing and Walking Frames
- K 9**
Ligament and Tendon Repair Implants
- K 10** Spectacle Frames
- Y 4** Mandibular Advancement Device(Anaesthetic and Respiratory Devices)
- Y 10** Insoles (Made Direct from Casts) (Technical Aids for Disabled Persons)
- Y 13** Postural Support Products(Technical Aids for Disabled Persons)
- Y 15** Splints (Limb/Body/Ear)/Collars(Single Use)

SYSTEM AND PROCEDURE PACKS (ARTICLE 12)

Please note that the following products will not be covered by Article 12, if they are assembled from any devices which do not contain the CE marking. The list is for guidance only and there are likely to be many more products covered by Article 12 than just those listed here. If you cannot find an appropriate code for a system or procedure pack needing to be notified please enter a brief description, and what is the intended use of the device(s), in **section 9a** of form RG2.

- L 1 Ward Dressing Packs
- L 2 Theatre Dressing Packs
- L 3 Oral Hygiene Packs
- L 4 First Aid Kits
- L 5 Prescribed Spectacles
- L 6 Cerebrospinal Fluid Filter With Syringe
- L 7 Ophthalmic Surgical Procedure Packs
- L 8 Orthodontic Procedure Packs
- L 9 Skin Traction Kits
- L 10 Surgical Procedure Packs (includes instruments supplied singularly)
- X 5 Theatre Drape Packs(Single Use)
- X 6 Needle Exchange Packs (Single Use)
- X 11 Endoscopes/Endoscopic Instruments And Accessories (Electro-Medical Mechanical Devices)
- X 14 Orthoses and Prostheses Procedure Packs (Single Use)
- X 18 Blood Specimen Collection Kits (Single Use)

In line with the requirements of the Hampton Report on Reducing Administrative Burdens - Effective Inspections and Enforcement, MHRA keeps its guidance documents under constant review. If you have any feedback, particularly on the presentation, accessibility or clarity of any of our guidance notes or bulletins please inform the contact person indicated at the end of the individual document.