

DRUG DEVICE DEMARCATION

Further information and interpretation is included in MEDDEV.2.1/3 an EC guidance document available from the European Commission.

DEVICE	PREVIOUS CONTROL	CURRENT CONTROL	COMMENT
1. Contact Lens Care Products a. Disinfecting b. Cleaning solutions c. Rinsing solutions d. Hydrating solutions e. Wetting agents f. Comfort drops	MA MA MA MA MA MA	MDR MDR MDR MDR MDR MDR	Considered to be accessories to medical devices when used with contact lenses. However they are medicinal products if therapeutic claims are made
2. Other Ophthalmics a. Artificial tears b. Fluorescein ocular strips c. Injectable fluorescein d. Rose Bengal e. Solution for preserving corneal material prior to transplant f. Ocular endotamponades g. Viscoelastic/viscosurgical products	MA MA MA MA None MDR MA	MA MA MA MA see comment MDR MDR	Commission guidance suggests that such products should be considered to be medicinal products
3. Surgical Dressings a. Non-medicated b. Medicated	MDR MA	MDR MDR/MA	Depends on manufacturer's claim
4. Sutures and Ligatures a. Absorbable b. Non-absorbable c. Biological Sealants	MA MDR MA	MDR MDR MA/MDR	Depends on mode of action.
5. Resorbable bone plates/poly(lactic/polyglycolic acid)	MA	MDR	
6. Hard tissue scaffolds a. Hydroxyapatite with/out collagen b. Calcium phosphate with/out collagen c. Bioglas	MA MA MA MA	MDR MDR MDR MDR	
d. Coral e. Cartilage repair systems	MA	MA/MDR	Depends on mode of action
7. Soft tissue fillers a. Collagen b. Silicone elastomer dispersions, eg Bio/uroplastique	MA MA	MDR MDR	

Note MA = Medicines Act 1968, Medicines for Human Use Regulations 1994 (SI 1994 No 3144) and Directive 65/65/EEC

MDR = Medical Devices Regulations 2002 (SI 2002 No 618) and Directive 93/42/EEC

DEVICE	PREVIOUS CONTROL	CURRENT CONTROL	COMMENT
8. Bone cements a Polymethylmethacrylate with/out antibiotic	MA	MDR	
9. Joint Replacements coated with a Hydroxyapatite/calcium phosphate b Bone growth factor (Beta BGF) c Genetically engineered BGF	MDR MDR MDR	MDR MDR MDR	Coatings of human origin are not covered by the MDR. (b) and (c) used alone are controlled by MA
10. Inhalation devices a Prefilled Metered dose inhalers b Chamber spacers for use with metered dose inhalers c Spinhalers - } refillable d Diskhalers - } refillable e Other empty or re-fillable inhalers (non powered)	MA MDR MDR MDR MDR	MA MDR MDR MDR MDR	(b) (c), (d) & (e) may be sold with medication and their performance/drug delivery will be assessed by MHRA
11. Powered Nebulisers a Device b Medication	MDR MA	MDR MA	
12. Insulin injection a Disposable Pen injectors integral with insulin cartridge b Re-usable insulin pens c Sterile Single use syringes (empty) d Insulin	MA MDR MDR MA	MA MDR MDR MA	
13. Blood Bags a Sterile empty b Sterile with anticoagulant	MDR MA	MDR MDR	
14. Dialysis devices a Device b Peritoneal solution including CAPDs c Haemodialysis solution d Haemofiltration solution	MDR MA None MA	MDR MA MDR MA	
15. Anaesthetic gases and oxygen cylinders a Pipeline/manifolds/AGSS b Bulk supply c Gas including cylinder	* NHSE MA	* NHSE MA	*UK position is that they are not covered by the MDR. This may not be the position throughout Europe. NHS Estates have responsibility within DH for fixed installations
16. Monoclonal antibodies a In-vitro diagnostics b Immunotoxins	None MA	See comment MA	IVD Directive which came into force from June 2000

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17. Human tissues a. Dura grafts b. Skin fibroblasts c. Bone	MA None None	MA * *	*These products are not covered by the Medical Devices Regulations 2002. Contact MHRA in the first instance
18. Dental Products a. Pit and Fissure Sealants b. Root Canal Sealers: Medicated/Non-medicated c. Root canal dressings (eg polyantibiotic pastes, antiseptics) d. Pulp capping material e. Dry Socket Preparation f. In-vivo diagnostics, eg disclosing tablets g. Haemostatic Agents and Astringents h. Retraction Cords: Medicated /Non-medicated i. Fluoride Preparations: eg Tablets, gels, varnishes j. Hard tissue scaffolds k. Desensitising agents: physical/pharmacological l. Periodontal dressings: Medicated/non medicated m. Periodontal Antibacterials: eg Gels, Ointments, fibres n. Varnishes: Protective/Drugs delivery o. Toothache Preparations p. Artificial Saliva q. Mouth ulcer preparations: medicated/non-medicated r. Antibacterial Mouthwashes/ Gels	MA MA MA MA MA MA MA/MDR MA MA MA MA/MDR MA MDR/MA MA MA MA MA	MDR MDR MA MDR/MA MDR/MA MA MA/MDR MDR MA MDR/MA MDR MA MA MA/MDR MA	If used for drug delivery then product covered by MA. Depends on product mode of action, see EC guidance. Depends on mode of action Depends on primary purpose
19. Contraception Products a. IUDs without action b. Diaphragms c. Condoms with/out spermicide d. IUDs with hormone action e. Spermicidal preparations eg creams pessaries, sponge film	MA MDR MDR MA MA	MDR MDR MDR MA MA	Where primary purpose is a drug delivery system
20. Impregnated Devices a. Antithrombotic coatings gelatin/heparin/protein b. Bacteriological coatings chlorhexidine/benzalkonium chloride/silver/salts/ antibiotics	MDR MDR	MDR MDR	

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DEVICE	PREVIOUS CONTROL	CURRENT CONTROL	COMMENT
21. Disinfectants a. Topical Disinfectants b. Disinfectants specifically for Medical Devices	MA MDR	MA MDR	Relationship/overlaps with the proposed Biocidal Products Directive currently under review
22. Plasma volume expanders	MA	MA	
23. In-vivo Diagnostic Agents a. X-ray contrast Media including MRI b. Barium meal c. other in-vivo imaging agents d. labelled urea for H pylor test e. gases for lung function tests	MA MA MA MA MA	MA MA MA MA MA	
24. Transdermal patches a. Disposable with medicament b. Iontophoresis Device (non disposable/reusable)	MA MDR	MA MDR	
25. Irrigation solutions including those used in the eye	MA	MDR	For mechanical rinsing purposes but if solution contains a pharmacologically active substance for the major indication then the product is covered by MA
27. 'Activated' Medicinal Products a. Medicinal Product b. Activating device eg laser	MA MDR	MA MDR	
28. Administration Devices a. Medicine Spoons b. Droppers c. Oral syringes d. Eye baths	MDR MDR MDR MDR	MDR MDR MDR MDR	These products are covered by MDR even though they may be supplied in the same pack as the medicine unless they form the closure of the container (eg dropper)
29. Agents for transport nutrition and storage of organs intended for transplantation	None	*	Commission guidance suggests that such products should be considered to be medicinal products
30. Artificial Skin systems	None	MDR/?	Products, which do not contain material of human material, will be covered by the Medical Devices Regulations. Otherwise consult with MHRA.
31. Viscoelastic gels for joint lubrication	MA	MA/MDR	Depends on mode of action

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