

A Notified Body for medical devices with ancillary medicinal substances

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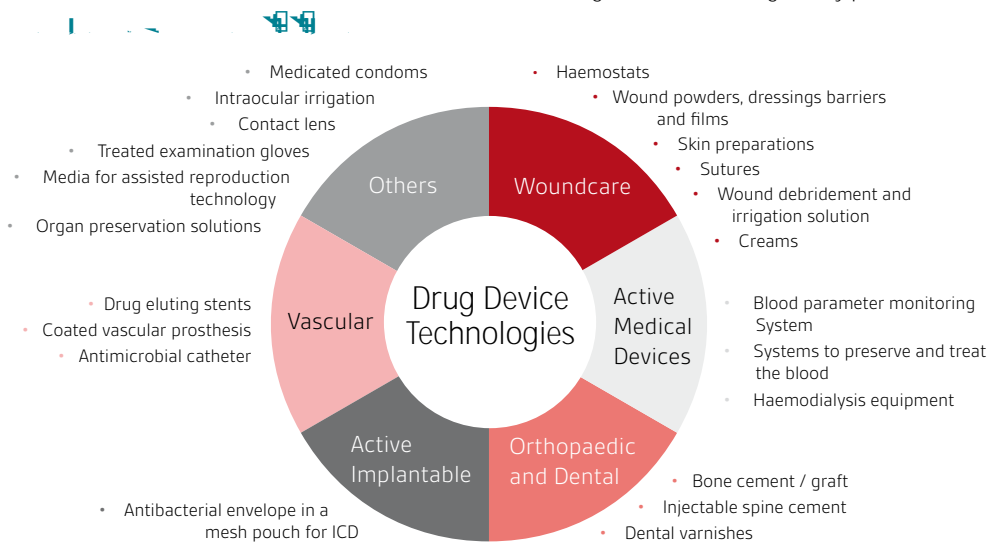
BSI specializes in medical devices with ancillary medicinal substances

Experience and expertise

BSI recognises that regulatory requirements for manufacturers of medical devices incorporating medicinal substances can be challenging. With a long history in this field and a vast range of certified devices, BSI has the expertise and knowledge to guide you through this specialized process.

BSI understands that the addition of an ancillary medicinal substance to your device will bring added benefits but that the regulatory process will be more demanding.

BSI is proud to offer a full Notified Body service in this area. Our dedicated in-house team of experts are here to guide you efficiently through this intricate regulatory process.



Gentamycin
 Human Serum Albumin
 Chlorhexidine
 Fluoride
 Lidocaine
 Thrombin, Growth Factors, recombinant peptides

Heparin
 Silver, Triclosan, Polyhexanide, Idoine
 Nicotinamide, Hydrogen peroxide
 Paclitaxel, Sirolimus, Novolimus
 Benzocaine,
 Erythromycin, Vancomycin, Doxycycline
 Rapamycin

Allopurinol, Mannitol, Adenosine
 Herbal medicines
 Dexamethasone

Classification

Early classification of medical products containing or delivering drug substances is essential in order that the appropriate regulatory path is determined:

Medical products designed to deliver drugs, supplied without the drug itself are regulated as medical devices, e.g. infusion pump.

Medical products designed to deliver drugs, supplied with the drug combined, are regulated as medicinal products, e.g. sub-dermal contraceptive implants and insulin-filled syringes.

Medical products which incorporate as an integral part a substance which, if used separately, can be considered to be a medicinal product and which is liable to act on the human body are regulated as Medical Devices, e.g. catheters coated with heparin.

To ensure an accurate classification you must consider the following questions:

