

Technical Data Sheet

Product(s):

Geistlich Bio-Oss®, Geistlich Bio-Oss Pen® and Geistlich Bio-Oss® Collagen

Revision: 00

Product line(s)	Geistlich Bio-Oss® Geistlich Bio-Oss Pen® Geistlich Bio-Oss® Collagen	
Type	Medical Devices <i>Non-Active Implants, Bone Substitute</i>	
Characterisation	- Biocompatible and biodegradable - Sterile and single-use - Free of Phtalates - Free of Latex	
Accessories	No	
Risk class	III	
Regulatory compliance	- Council Directive 93/42/EEC (MDD) and correlated standards / guidelines / guidances to meet the Essential Requirements of Annex I - ISO 13485:2016 - ISO 9001:2015 - Swiss Therapeutic Products Act, Swiss Medical Devices Ordinance - Commission Regulation (EU) No 722/2012 - Regulation (EC) No 1069/2009 - Commission Regulation (EU) No 207/2012	
Notified Body	TÜV SÜD Product Service GmbH (identification number: 0123) 	
Certificate (acc. MDD Annex II (4))	Geistlich Bio-Oss®	G7AO 039446 0092 Rev. 00 G1 039446 0086 Rev. 01
	Geistlich Bio-Oss Pen®	G7AO 039446 0093 Rev. 00 G1 039446 0086 Rev. 01
	Geistlich Bio-Oss® Collagen	G7AO 039446 0094 Rev. 01 G1 039446 0086 Rev. 01
Legal Manufacturer	Geistlich Pharma AG	
Contact data	Bahnhofstrasse 40 6110 Wolhusen, Switzerland +41 (0)41 492 55 55 info@geistlich.com https://www.geistlich-pharma.com/	
European Authorized Representative / Importer	Geistlich Biomaterials Vertriebsgesellschaft mbH Schöckstrasse 4 76534 Baden-Baden, Germany	

Intended Purpose	Described in the Instructions for Use of - Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® - Geistlich Bio-Oss® Collagen
Composition	Geistlich Bio-Oss® is a natural bone mineral of bovine origin. Geistlich Bio-Oss® is available as granules of spongy bone and as a spongy bone block. The granules are also available in an applicator as Geistlich Bio-Oss Pen®. Because of its natural origin, Geistlich Bio-Oss® is chemically as well as structurally comparable to the human bone mineral. Major component of implantable Geistlich Bio-Oss® granules: biologically derived apatite.
	Geistlich Bio-Oss® Collagen is a mixture of 90 wt-% Geistlich Bio-Oss® (granules of the size 0.25 – 1 mm) and 10 wt-% porcine collagen fibers in a block form.
Sterilisation	Sterilized using irradiation
Storage Conditions	At 15°C to 25°C, keep dry, keep away from sunlight
Shelf Life	Expiry date is indicated on the packaging label
Intended User	Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® should only be used by licensed dentists/physicians familiar with bone augmentation procedures.
	Geistlich Bio-Oss® Collagen is to be used by licensed dentists/physicians trained in surgical management of hard tissue defects in the oral-maxillofacial surgery.
Handling	The handling of the products is described in the Instructions for Use. The general principles of sterile handling and patient medication must be followed when using the products. - Do not re-use. - Do not resterilize. - Do not use if package is damaged or opened unintentionally. - Do not use after expiry date. - Discard any unused material.
Disposal	Disposal should be handled in an environmentally sustainable manner according to local, state and official regulations. Where applicable, legal requirements for the separation of materials for material recycling or other uses must be considered. Hazardous bio-waste from contaminated devices or packaging materials should be disposed of safely in appropriate containers.

For further information please consult the current version of the appropriate Instructions for Use: ifu.geistlich-pharma.com or in the device package.

Note: The products in scope are medical devices to which the format of a Material Safety Data Sheet (MSDS) is not applicable.

leading regeneration

Geistlich

On behalf of Geistlich Pharma AG,

Chantal Benz

Senior Regulatory Affairs Manager

Marco Steiner

Group Lead & Deputy Director Regulatory Affairs