1 - Intended use and expected clinical benefits
The 'dental implant' device is intended to restore normal chewing function following edentulousness and maintain the healthy condition of the natural dentition. Endosseous dental implants anchor into the maxillary or mandibular bone, a process known as osseointegration, and replace the natural roots of the teeth, forming a stable base for the permanent attachment of the abutment and its prosthesis.

1.1 – Materials used
Patients are exposed to contact with the materials constituting the DM:

Titanio Gr. 4 ASTM F67

TABLE 1 Chemical Requirements

Element	Composition[A], % (mass/mass)			
	Grade 1 UNS R50250	Grade 2 UNS R50400	Grade 3 UNS R50550	Grade 4 UNS R50700
Nitrogen, max	0.03	0.03	0.05	0.05
Carbon, max	0.08	0.08	0.08	0.08
Hydrogen, max[B]	0.015	0.015	0.015	0.015
Iron, max	0.20	0.30	0.30	0.50
Oxygen, max	0.18	0.25	0.35	0.40
Titanium	balance	balance	balance	balance

Titanio Gr. 5 ASTM F136

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

Its use is not recommended in patients with allergies or hypersensitivity to these materials

The device does not contain or incorporate:
- a medicinal product including a derivative of human blood or plasma
- human tissues or cells, or derivatives thereof, or
- tissues or cells of animal origin, or derivatives thereof, covered by Regulation (EU) No. 722/2012

Dental implants are made of Titanium Gr. 4 ASTM F67 or Gr. 5 ASTM F136.
codes TZP and TZ-EP where a nitriding process (TiN) is conducted only on the 1.8 and 2.2 diameter ball connection part.

2 - Warnings
Since DM is used in the application of implant procedures for functional and aesthetic rehabilitation resulting from the loss or congenital absence of one or more teeth, it should only be used by dentists with specialist training.
The device is sterile and must therefore be opened in a surgically suitable environment.
ISOMED devices have not been evaluated for compatibility and safety in magnetic resonance imaging (MRI) environments. The implants were not tested for heating, migration or the possibility of creating MRI image artefacts in magnetic resonance imaging (MRI) environments. The safety of ISOMED implants in the magnetic resonance imaging (MRI) environment is unknown. MRI scanning in a patient who has these devices may cause heating, migration or the possibility of creating artefacts in the MRI image.

3 - Precautions
A thorough study of the case, through clinical and radiographic investigations, is recommended. In addition to orthopantomography, CT scans or dental scans can be very useful in order to precisely highlight anatomical relationships at critical points, such as the course of the inner alveolar nerve, its emergence in the mental foramen and the maxillary sinuses.

4 - Restrictions on Use
Use only for its intended purpose.
Do not place implants where bone support is not adequate, in quantity and quality, to contain the implant. Carefully assess the patient's state of health, oral hygiene, smoking, possible malocclusion, bruxism and all those conditions and/or habits that may lead to implant therapy failure.
Implant surgery is not recommended for patients with the following conditions: arrhythmias, heart valve problems, angina or post-infarct patients, patients taking anticoagulants or antiplatelet agents.
Implant treatment cannot be used in the case of:
- pregnancy;
- transplantation for less than six months;
- serious neurological diseases;
- mental disorders;
- severe impairment of the immune system;

The device is disposable, reuse may compromise the safety features of the device making it unsuitable for its intended use. ISOMED explicitly declares DM disposable and assumes no liability for any re-use by users.

Do not use the device if the packaging is damaged or if the expiry date stated on the label has passed.

5 - Causes of failed osseointegration
Several factors can have a negative effect on implant osseointegration; some of these factors are: smoking, drug intake, poor oral hygiene, severe parodopathy, inadequate protein structures, peri-implatitis, systemic diseases such as decompensated diabetes, overheating of bone from improper use of drills, without adequate irrigation with cold physiological saline or use of obsolete drills.

6 - Causes of implant fracture
Pay close attention to the occlusion of the prosthesis on implants, especially to the transverse forces that can occur as a result of excessive intercuspation with absence of mandibular releases. These transverse forces have an injurious effect on the peri-implant bone with the formation of bone resorption bowls. The loss of bone support on the coronal side increases the lever arm and transverse forces can cause the implant to fracture. Another cause of implant fractures is an important disproportion between implant length and crown size, especially in the molar region, which undergoes enormous masticatory forces. The monophasic implants of Ø 2.5 - 2.9 - 3 - 3.5 mm are not to be loaded individually, they are used in groups while paying attention to prosthetic loads. Such implants can also break during screwing into the bone. It is recommended that the drill be drilled 1 mm beyond the length of the implant itself in order to prevent the fixture from getting stuck at the tip while the surgeon continues to screw the implant in with the chisel, causing it to fracture. For immediately loaded overdentures with monobasic ball implants having the function of stabilising the prosthesis, their use in the mandible and only for groups of 4 implants in the intraforaminal region is recommended.

7 - Patient information and traceability
Current regulations require the patient to be informed by the doctor about the risks related to the device and possible surgical complications, as well as the need for periodic check-ups and in case of unexpected situations. For the purposes of implant traceability, the package contains two labels with the device's identification data; one must be affixed to the patient's medical record and the second to the 'Personal Card'.
The warnings, precautions or measures to be taken by the patient or a healthcare professional in relation to
Mutual interference with reasonably foreseeable external influences, medical examinations or environmental conditions as well as information on the expected life of the device and any necessary follow-up are given at www.isomed.it

The summary relating to safety and clinical performance (SSCP) in accordance with art. 32 of Regulation (EU) 745/2017, is available in the Customer area of the website www.isomed.it. In the European database of medical devices EUDAMED (https://ec.europa.eu/tools/eudamed) it is possible to view the summary relating to the safety and clinical performance of "dental implant" devices, whose Basic UDI-DI is:

Impianti Monofasici	**805414464ID0001U2**
Impianti Bifasici	**805414464ID0002UF**
Impianti Zigomatici	**805414464ID0003UH**

The physician and/or patient must report any serious incidents occurring with the device to the ISOMED manufacturer and to the competent authority of the Member State where the user and/or patient is established.

8 - Storage Precautions
Store in a dry place and do not expose to direct sources of heat or sunlight.

9 - Disposal
In the case of DM disposal needs, one can proceed by referring to local laws concerning special medical waste at risk of contamination. The DM must be cleaned and sterilised before disposal.

CE 0426	REF DM Code	Manufacturer	LOT Lot number	UDI UDI code	Date of manufacture	www.isomed.it	Disposable
	Expiry Date	Sterile Barrier	STERILE R Ionising radiation sterilisation	Do not use if packaging is not intact	MD Medical Device		