TECHNICAL REPORT

ISO TR 10451

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Dental implants — State of the art — Survey of materials

Implants dentaires — État de l'art — Répertoire des matériaux

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 10451, which is a Technical Report of type 2, was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This document is being issued in the type 2 Technical Report series of publications (according to subclause G.6.2.2 of part 1 of the IEC/ISO Directives) as a "prospective standard for provisional application" in the field of dental implantology because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an "International Standard". It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.

A review of this type 2 Technical Report will be carried out not later than two years after its publication with the options of: extension for another two years; conversion into an International Standard; or withdrawal.

Annexes A, B and C of this Technical Report are for information only.

Introduction

In ISO/TC 106, a recommendation was made to form SC 8 with the purpose of establishing an International Standard on dental implants at the plenary meeting held in Solna (1984).

The work of preparing a Technical Report, type 2, was carried out in Milan (1985), Hong Kong (1986), Buenos Aires (1987) and Chicago (1988).

In addition to knowledge of basic medical sciences, dental implants also require extensive knowledge of the structure and function of the oral cavity, including soft and hard tissues.

Dental implants are located in the unique environment of the oral cavity, soft and hard tissues, and accordingly are in contact with different media:

— saliva and other contents of the oral cavity,

— crevicular fluid and the mucosa interface,

— bone and blood, and soft tissues.

The dental implant is influenced further by the chemical, physical and mechanical properties of the material of which it is made.

Dental implants have been used successfully for many years. However, since implantology is a developing discipline, coupled with the circumstance that there are inadequate data to produce a Standard, it was recommended, following the meeting in Milan, that a type 2 Technical Report be produced describing the present state of the art of the materials.

In addition to the properties of the materials, it was deemed advisable to include design and implantation procedures in the scope of this Report.

In order to fulfil all the requirements for a Standard, it was decided in Hong Kong in 1986 to provide the biological component in collaboration with FDI/ISO/TC 106 joint working Group on biological evaluation.

It is the intention of ISO/TC 106 that this Technical Report will be reviewed regularly in the light of technological advances and the availability of more data, with the ultimate objective of using it as a basis for an International Standard.

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Dental implants — State of the art — Survey of materials

1 Scope

This Technical Report surveys the materials used in the discipline of dental implantology.

Characterization sheets are included as product information guidelines for a standardized sampling of data related to materials and implantation procedures.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Technical Report. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this Technical Report are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms.*

ISO 5832-1:1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.*

ISO 5832-2:1978, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium.*

ISO 5832-3:1990, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.*

ISO 5832-4:1978, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy.*

ISO 5832-5:1978, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ISO 5832-6:1980, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy.*

ISO 5832-8:1987, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy.*

ISO 6474:1981, *Implants for surgery — Ceramic materials based on alumina.*

ISO/TR 7405:1984, *Biological evaluation of dental materials.*

ISO/TR 9966:1989, *Implants for surgery — Biocompatibility — Selection of biological test methods for materials and devices.*

3 Definitions

For the purposes of this Technical Report, the definitions given in ISO 1942-1 and the following definitions apply.

3.1 dental implant: Device specially designed to be placed surgically within or on the mandibular or maxillary bone as a means of providing resistance to displacement of a dental prosthesis. (ISO 1942-1:1989, definition 1.080)

NOTE 1 It can be either transgingival (with part of the implant emerging from gingiva for direct abutment), or fully embedded under the gingiva (only aiming at the support of a removal prosthesis).

3.2 transendodontic implant; transradicular implant: Rod specially designed and/or prepared to be inserted either through the root canal or through the root in the bone.

3.3 endosseous implant: (Dental) implant placed partly or entirely within bone.

3.4 fully embedded dental implant: Dental implant which is fully covered by gingiva or mucosa.

3.5 transgingival [transmucosal] implant: Dental implant that has extension(s) into the oral cavity through the mucosa for providing resistance to the displacement of a dental prosthesis.

3.6 subperiosteal implant: Dental implant placed between periosteum and the surface of the bone.

3.7 intramucosal implant: Dental implant placed into the soft tissue lining of the oral cavity.

4 Classification of materials

4.1 General classification

Implants may be of the following materials:

1) Metallic materials (see table 1);

2) Ceramic materials (see table 2);

3) Polymeric materials (see table 3);

4) Fibrous composite materials (see table 4);

5) Coating materials (see table 5);

6) Multiple combination of materials (see table 6).

4.2 Family

This classification has been assembled in the form of one table per family, each composed of six columns specifying

— Column 1: the number of the class, followed by the name of the basic chemical nature of the material.

— Column 2: the number of the sub-class in relation with the specific chemical composition grade of the material.

— Column 3: the International Standard reference, when applicable.

— Column 4: the designation of the materials, with an indication of their general chemical composition, their physical constitution and their basic manufacturing process.

— Column 5: the type of use of the implant concerned, with the material taken into account, subdivided as follows:

A transgingival (or transmucosal) implants,

B transendodontic (or diodontic) implants,

C embedded implants,

D subperiosteal implants,

with an indication of the corresponding level of advancement:

"E" = experimental,

"X" = currently in use.

— Column 6: possible comments, for instance, some particularities of constitution.

Table 1 — Metallic materials

1	2	3	4	5				6
Class	Sub-class	References	Form and composition	Use				Observations
				A	B	C	D	
1.1 Stainless steel	1.1.1	—	Cast stainless steel	—	X	X	—	—
	1.1.2	ISO 5832-1 modified	Wrought stainless steel	E	X	E		—
1.2 Commercially pure titanium	1.2.1	ISO 5832-2	Wrought titanium	X	X	X	E	—
	1.2.2	—	Cast and machined titanium	X	—	X	E	—
1.3 Titanium alloys	1.3.1	ISO 5832-3 modified	Wrought titanium, 6 aluminium, 4 vanadium alloy	X	X	X	E	—
	1.3.2	Document ISO/TC 150/1 N 117 Rev.	Wrought titanium, 5-aluminium, 2,5-iron alloy	E	E	—	—	—
1.4 Cobalt chromium alloys	1.4.1	ISO 5832-4	Cast cobalt chromium – molybdenum alloy	E	E	X	X	—
	1.4.2	ISO 5832-4 modified	Wrought cobalt chromium – molybdenum alloy	E	E	X	X	—
	1.4.3	ISO 5832-5	Wrought cobalt chromium – tungsten – nickel alloy	—	X	X	X	—
	1.4.4	ISO 5832-6	Wrought cobalt – nickel – chromium – molybdenum alloy	—	X	X	X	—
	1.4.5	ISO 5832-8	Wrought cobalt – nickel – chromium – molybdenum – tungsten – iron alloy	—	X	—	—	—
1.5 Tantalum	1.5.1	—	Pure tantalum	X	X	E	—	—
1.6 Niobium	1.6.1	—	Pure niobium	E	E	E	—	—
	1.6.2	—	Niobium – zirconium alloy	E	E	E	—	—
1.7 Gold	1.7.1	—	Gold alloy	X	E	E	E	—
1.8 Platinum	1.8.1	—	Pure platinum	E	E	E	E	—
	1.8.2	—	Platinum alloy	E	E	E	E	—

Table 2 — Ceramic materials

1	2	3	4	5				6
Class	**Sub-class**	**References**	**Form and composition**	**Use**				**Observations**
				A	B	C	D	
2.1 Ceramic based on alumina	2.1.1	ISO 6474 modified	Dense sintered crystalline alumina (Al 203)	X	X	X	—	—
	2.1.2	—	99,9 % pure porous alumina	E		E	—	—
	2.1.3	—	97 % pure porous alumina	E	—	E	—	—
	2.1.4	—	Zirconia reinforced alumina	E	E	—	—	Partially stabilized
	2.1.5	—	Calcium phosphate alumina	—	—	E	—	—
	2.1.6	—	Single crystal of alumina	X	X	—	—	—
2.2 Ceramic based on glass	2.2.1	—	Porous vitroceramic	E		E	—	—
	2.2.2	—	Dense vitroceramic	E	—	E	—	—
2.3 Ceramic based on calcium phosphate	2.3.1	—	Dense sintered hydroxy apatite	X	—	X	—	Not biodegradable
	2.3.2	—	Porous sintered hydroxy apatite	X	—	—	—	Not biodegradable
	2.3.3	—	Dense sintered beta whitlockite	—	—	X	—	Biodegradable
	2.3.4	—	Porous sintered beta whitlockite		—	X	—	Biodegradable
	2.3.5	—	Other types	E	—	X	—	Biodegradable
2.4 Ceramic based on calcium carbonate	2.4.1	—	Porous sintered calcium carbonate	—	—	X	—	—
	2.4.2	—	Natural porous calcium carbonate	—	—	X	—	—
2.5 Ceramic based on zirconia	2.5.1	—	Alumina stabilized zirconia	E	—	—	—	—
	2.5.2	—	Yttria partially stabilized zirconia	E	—	—	—	—
	2.5.3	—	Ceria partially stabilized zirconia	E	—	—	—	—

Table 3 — Polymeric materials

1	2	3	4	5				6
Class	Sub-class	References	Form and composition	Use				Observations
				A	B	C	D	
3.1 Polysiloxane	3.1.1	—	Polysiloxane heat cured	—	—	X	—	—
3.2 Polysulfone	3.2.1	—	Porous polysulfone	—	—	X	—	—
	3.2.2	—	Non-porous polysulfone	—	—	X	—	—
3.3 Polymethacrylate	3.3.1	—	Methacrylate	—	—	E	—	—

Table 4 — Fibrous composite materials

1	2	3	4	5				6
Class	Sub-class	References	Form and composition	Use				Observations
				A	B	C	D	
4.1 Composite based on carbon/carbon	4.1.1	—	Porous pyrolytic carbon matrix reinforced with carbon fibres	E	E	E	—	With thin pyrolytic carbon coating
4.2 Composite based on carbon/ceramic	4.2.1	—	Porous silicon carbide matrix reinforced with carbon fibres	E	E	E	—	With thin silicon carbide coating

Table 5 — Coating materials

1	2	3	4	5				6
Class	Sub-class	References	Form and composition	Use				Observations
				A	B	C	D	
5.1 Titanium coating	5.1.1		Titanium plasma sprayed coating	X	—	—	—	Onto titanium substrate
	5.1.2		Titanium coating	E	—	—	E	Onto metallic substrate
5.2 Carbon coating	5.2.1		Pyrolytic carbon coating by CVD or CVI process	E	—	E	—	Onto carbon fibre substrate
	5.2.2		Ion beam deposited carbon	E	—	—	—	For thin coating onto any material
	5.2.3		Pyrolytic carbon and silicon carbide co-deposited	E	—	—	—	For thick coating onto polycrystalline graphite substrate
5.3 Calcium phosphate coating	5.3.1		Hydroxy apatite deposited by chemical liquid spray process (CLD)	E	—	E	—	For thin coating onto porous material
	5.3.2		Hydroxy apatite sintered coating	E	—	E	—	—
	5.3.3		Plasma sprayed hydroxy apatite	X	E	—	X	Onto titanium and cobalt chromium alloys substrate
	5.3.4		Sputtered calcium phosphate	E	—	—	—	Usually onto titanium substrate
	5.3.5		Calcium phosphate deposited by electrolytic process	E	—	—	—	Onto titanium substrate
5.4 Alumina coating	5.4.1		Sputtered crystalline aluminium oxide	E	—	—	E	With metallic substrate
	5.4.2		Amorphous deposited aluminium oxide	X	X	X	X	With metallic substrate
	5.4.3		Porous alumina (Al 203)	E	E	—	—	With titanium substrate
	5.4.4		Porous coating 99,9 % pure alumina	E	E	—	—	With titanium and tantalum substrate
	5.4.5		Porous coating 97 % pure alumina	E	E	—	—	With titanium and tantalum substrate
	5.4.6		Cermet (Al 203 + Ti)	E	E	—	—	—
5.5 Glass coating	5.5.1		Silica based ceramic coating	E	E	—	E	Fused onto alloy substrate

Table 6 — Multiple combination of materials

1	2	3	4	5				6
Class	Sub-class	References	Form and composition	Use				Observations
				A	B	C	D	
6.1 Metallic core with alumina material	6.1.1	—	Porous sintered polycrystalline alumina onto titanium alloy core	E	—	—	—	—
	6.1.2	—	Porous sintered polycrystalline alumina onto cobalt chromium alloy core	E	—	—	—	—
	6.1.3	—	Porous sintered polycrystalline alumina onto tantalum core	E	—	—	—	—
6.2 Metallic core with calcium phosphate material	6.2.1		Sintered dense hydroxy-apatite onto titanium alloy core	X	—	—	E	—
	6.2.2	—	Sintered dense hydroxy-apatite onto cobalt chromium alloy core	X	—	—	E	—

5 Characterization sheets

5.1 General

Four characterization sheets, of one page each, list the data which should be taken into account for evidence of acceptable biocompatibility and efficacy for materials used for dental implants.

They should be taken into account as a guide for a standardized sampling of data related to materials and implantation procedures. The four characterization sheets are as follows:

— Sheet I: chemical, physical and mechanical characteristics of constituent materials;

— Sheet II: behaviour of constituent materials in biological media;

— Sheet III: mechanical characteristics of the materials and the shape of dental implants;

— Sheet IV: influence of the design and the implantation procedures on the behaviour of dental implants in biological media.

While respecting the four-page limitation, this presentation will

a) avoid the confusion between the constituent materials and the dental implant itself;

b) separate, in both cases, chemical, physical and mechanical characteristics from the biological aspects (see figure 1).

NOTE 2 Annex B gives explanatory notes for filling in the four characterization sheets.

5.2 Characterization sheet I

The first sheet is devoted to the chemical, physical and mechanical characteristics of the constituent materials. It is presented in the form of a table with six columns:

— Column 1: the classification for the material is entered by table number of the general classification (table 1 to table 6) followed by the class and sub-class. The preferred way of use and the current state of progress are also noted clearly in order to facilitate completion of the sheets.

— Column 2: the type of material is indicated in more detail by reference to the six classification tables and any other recognized Standard.

— Column 3: the appropriate wording or symbol is inserted, from the list given in the narrower column to show the manufacturing process.

— Column 4: in this column the chemical nature of the constituent materials is entered.

— Column 5: details of the physical properties are filled in, as appropriate, with symbols and units.

— Column 6: details of the mechanical properties are given as appropriate with symbols and units, deduced from the tests carried out with samples from the constituent materials. The values given will be reached from recognized test procedures, citing the reference, if such is the case, of the corresponding Standard.

5.3 Characterization sheet II

The second sheet is devoted to the behaviour of the constituent materials in biological media. It is presented in the form of a table with four main columns:

— Columns 1 and 2: the number of the table, class and sub-class and the type of material under consideration are given in the same way as for characterization sheet I from the general classification (table 1 to table 6).

— Column 3: this column is for the *in vitro* tests on samples of constituent materials, with a left-hand section giving the evaluation procedures and their reference. The right-hand section summarizes the results. References of corresponding reports, if they exist, should also be given. (These tests are specified in the "Matrix of device applications and potentially applicable biocompatibility test procedures" which were last updated at the ISO meeting of TC 150/WG 4, *Biocompatibility and haemocompatibility*, in Paris in November 1988.)

— Column 4: a similar layout is used for the *in vivo* tolerance tests as that used in column 3 for the *in vitro* tolerance tests.

Sheet II when filled in represents the "Biological identity card" of the constituent material, and may be common to several shapes of implants using the same material.

When an International Standard procedure is lacking, it is permitted to use a procedure standardized nationally in the country concerned, or one specifically established by the manufacturer within the scope of the dental implant application.

Results should be collated together, with reference to publications and an indication of the typical aspects which apply to dental implants (and, if necessary, as they apply to other surgical applications).

5.4 Characterization sheet III

The third sheet with its five main columns is devoted to data on mechanical characteristics of the materials and the shape of dental implants.

— Columns 1 and 2: repeat the details entered in sheets I and II.

— Column 3: draw a simple diagram of the implant to show whether it is used as a blade, a screw, a cone or whatever.

Give the main dimensions to indicate the largest and smallest sizes used.

List the other aspects about the implant which are noted in this column.

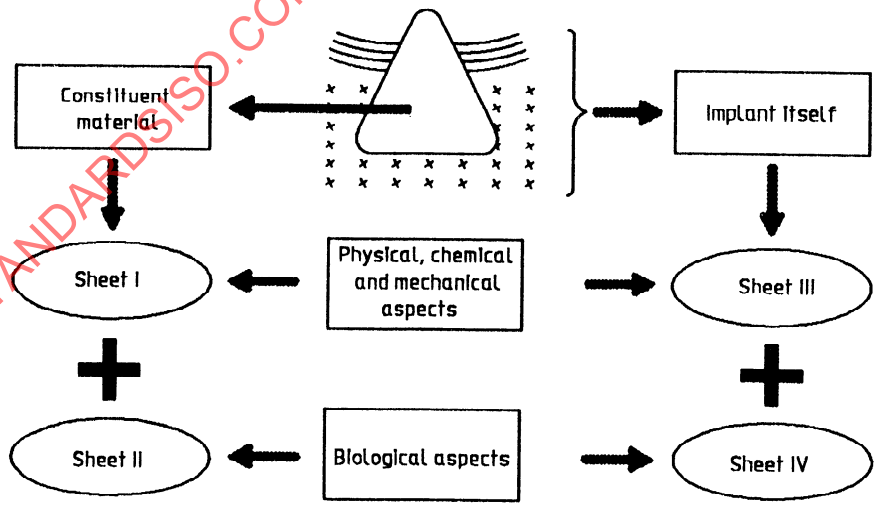

Figure 1

— Column 4: this column specifies the maximum stresses that the implant will support: either when implanted (impact stress, torsional or flexural stress) or when sited in place (cyclical stresses of compression, torsion or flexion) under functional use, or when retrieval eventually occurs, such as following pathological problems.

  A simple drawing would help to show the direction of these forces upon any part of the implant when the superstructure is added.

— Column 5: in the left-hand area, the mechanical test procedures are defined, with reference to the specific test on the implant used by the manufacturer (if a Standard procedure does not exist). If possible, illustrate with a sketch.

  The tests should also take into account the force needed to tear off any superadded fixture from the dental implant and give some description of the condition of its surface.

  The right-hand area should include details about the results obtained by the preceding tests. In particular, it is necessary to know the behaviour of the implant with crushing, bending, twisting, impacting and its fatigue strength in a simulated biological medium.

  The effect of size on these findings should be related to an implant in the middle of the range for size.

5.5 Characterization sheet IV

The fourth sheet, again comprising five main columns, reports the biological performance of the material related to the shape of the actual implant used, when put into a functional situation. It covers influence of design and implantation procedure on the behaviour of the dental implants in biological media.

— Columns 1 and 2: repeat the details entered in sheets I, II and III.

— Column 3: draw a diagram giving the general shape of the dental implant when finally in occlusion (embedded, transgingival, transendodontic or subperiosteally situated).

— Column 4: indicate the surgical procedure when implanting, such as screwing, impacting or embedding. Also indicate the retrieval procedure.

— Column 5: in the left-hand area, give references to standards or to specific procedures used to test *in vivo* the actual implant in the animal situation, with a reference to the number and the species involved.

  If available information should be given regarding a clinical evaluation of an implant similar to that under consideration and in accordance with standardized protocols or specific procedures when used as advised by the manufacturer.

  The right-hand area summarizes the state of the art, progress with animal experiments and the clinical uses of the implant, with indications of:

  the number of surgical teams,

  the number of implantation cases,

  the follow-up period (range and average),

  the success rate set against duration from the time of actual implantation.

  This column is completed by an overall comment about the general behaviour of the implant and the typical outcome when as recommended.

Sheet I — Chemical, physical and mechanical characteristics of constituent materials

1	2	3		4	5		6	
Reference to classification tables	Type of material	Manufacturing process		Chemical characteristics, composition and properties	Physical characteristics[1]		Mechanical characteristics[1]	
		Designation	Symbol		Parameters	Symbol	Parameters	Symbol
Table:	Designation of the table:	Moulding	—	Components distribution	Density (g/cm³)	ϱ	Ultimate tensile strength	R_m
Class:	Reference to Standards:	Wrought	—	Chemical composition	Porosity (%)		Flexural strength	σ_B
Sub-class:	Morphological aspect:	Cold working	—	Chemical impurities	Microstructure		Compressive strength	σ_C
Preferred use:	Amorphous	Polymerization	—	Electro-chemical properties	Crystallite size	Å	Shear strength	τ_S
	Crystalline	Physical vapour deposition	PVD		Morphology		Elastic modulus (Young modulus)	E
	Composite	Chemical vapour deposition	CVD		Electrical resistance		Strain to fracture	
	Coating	Chemical vapour infiltration	CVI		Thermal conductivity		Yield strength	
		Electron beam deposition	EBD		Thermal coefficient of expansion	α	Elongation (%)	A
		Ion beam deposition	IBD		Specific heat	C	Reduction of area (%)	
		Sintering	—		Melting range	T_m	Hardness	HV
		Sputtering	—		Softening point		Resilience	
		Plasma deposition	—		Sublimation point		Fatigue limit/fracture strength (%)	
		Spray deposition	—		Surface free energy		Strain energy to fracture	
		Enamelling	—		Wettability		Critical stress intensity factor	K_{1C}
		Chemical liquid deposition	CLD		Ageing		Adherence strength	
					Cat scan			
					Radio-opacity			

1) Where appropriate.

Sheet II — Behaviour of constituent materials in biological media

1	2	3		4	
Reference classification tables	**Type of material**	*In vitro* **tolerance tests**		*In vivo* **tolerance tests**	
		Test procedures	Results	Test procedures	Results
Table: Class: Sub-class: Preferred use:	Designation of the table: Reference to standards: Morphological aspect: Amorphous Crystalline Composite Coating	Refer to *in vitro* test procedures of "Biocompatibility and haemocompatibility" matrices (ISO/TR 9966 and appropriate tests in ISO 7405) Refer to *in vitro* test procedures recommended by the manufacturer	Refer to specific reports and published papers Results applicable to dental implants	Refer to *in vivo* test procedure of "Biocompatibility and haemocompatibility" matrices (ISO/TR 9966 and appropriate tests in ISO 7405) Refer to *in vivo* test procedures recommended by the manufacturer	Refer to specific reports and published papers Results applicable to dental implants

Sheet III — Mechanical characteristics of materials and shape of dental implants

1	2	3	4	5	
Reference to classification tables	**Type of material**	**State of implant**	**Mechanical specifications**	**Mechanical tests**	
				Test procedures	Results
Table: Class: Sub-class: Preferred use:	Designation of the table: Reference to standards: Morphological aspects: Amorphous Crystalline Composite Coating	Diagram of dental implant Sizes Manufacturing process: Cold working Casting Machining Surface finishing Size particles Packaging — Marking Labelling Sterilization	As related to dental implants	Refer to applicable international Standards and the test procedures recommended by the manufacturer	Refer to specific reports and published papers Results applicable to dental implants

Sheet IV — Influence of design and implantation procedure on behaviour of dental implants in biological media

1	2	3	4	5	
Reference to classification tables	**Type of material**	**Stress diagram of dental implant**	**Surgical implantation methods and instrumentation**	**Biological evaluation**	
				Test procedures	Results
Table: Class: Sub-class: Preferred use:	Designation of the table: Reference to standards: Morphological aspects: Amorphous Crystalline Composite Coating		Placement	Refer to applicable international Standards and the test procedures recommended by the manufacturer	Refer to specific reports and published papers Results applicable to dental implants