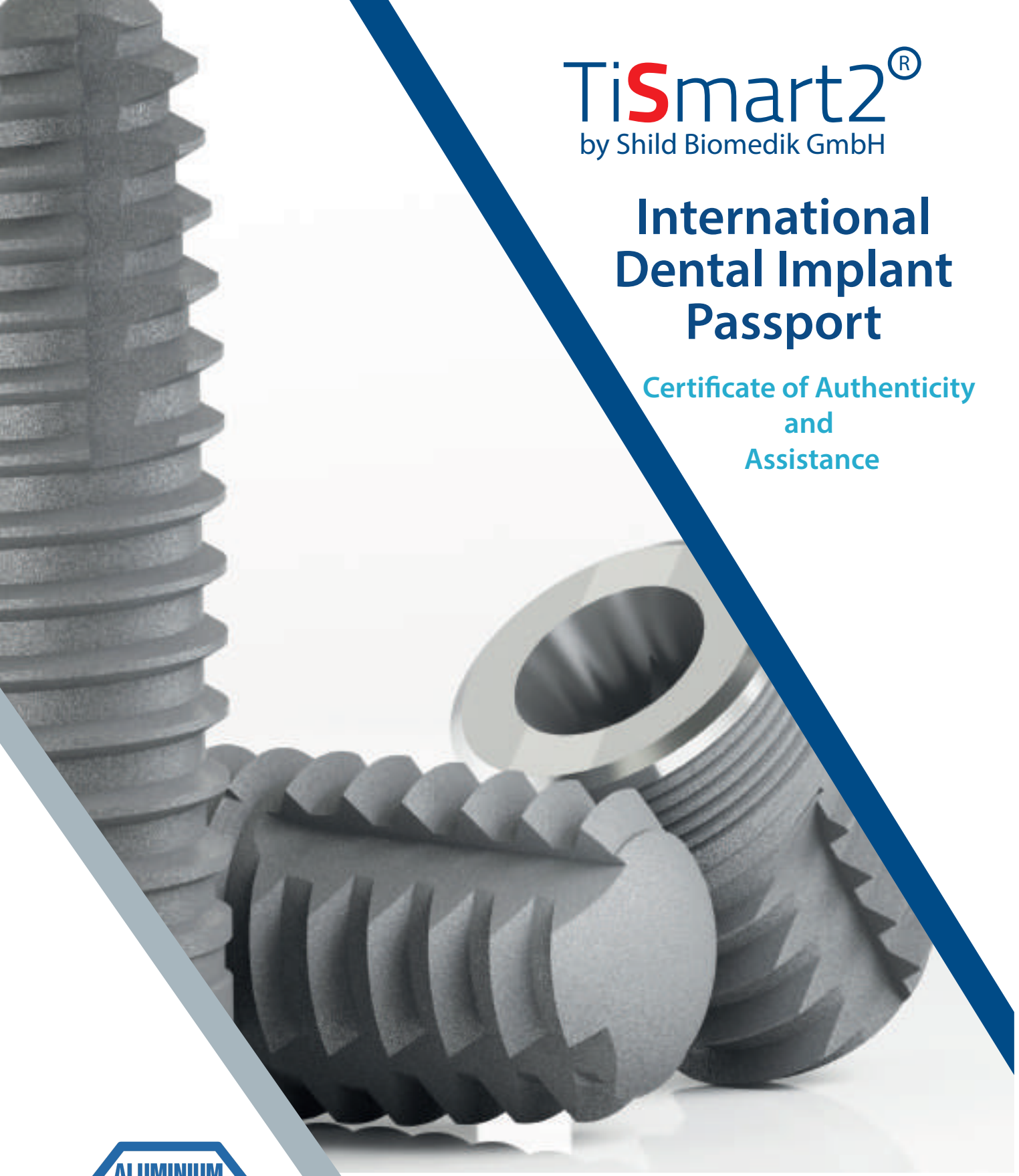
TiSmart2®
by Shild Biomedik GmbH

International Dental Implant Passport

Certificate of Authenticity and Assistance



ALUMINIUM FREE PROCESSING

Patient name

Address

Telephone

Date

Stamp of dentist's office

Implants position

RS	LS
18 17 16 15 14 13 12 11	21 22 23 24 25 26 27 28
48 47 46 45 44 43 42 41	31 32 33 34 35 36 37 38
RI	LI

Description of rehabilitation treatment of prosthetic implant

IMPLANT TYPE Diam./Length	Apply adhesive label contained inside the package
POSITION	
SURGERY DATE	
REOPENING DATE	
TRASMUCOSAL SCREW	
PROSTHESIS DATE	
Code ABUTMENT, CONNECTION, OTHERS	Apply adhesive label contained inside the package

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Subsequent Controls

Date	Observations

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Date	Observations

Subsequent Controls

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Quality Certificate

By means of present Dental Card, the by Shild Biomedik GmbH Company, which system of quality management complies with standard UNI CEI EN ISO 13485:2012, certifies that implantable medical devices used for your solution belong to the IIb risk class, in accordance and in compliance with regulation 8 of annex IX of Directive 93/42/CEE, 2007/47/CE with subsequent amendments (implemented in Italy with Legislative Decree 24 of February 1997, n.46, and subsequent amendments).

The implants and prosthetic components are manufactured in accordance with the Quality System that satisfies the requirements of Annex II of Leg. Decree n. 46 del 24/02/97 and subsequent amendments, as per Certificate n. MED 26020 released on 2006/12/19 by Notified Body n. 0476 CERMET.

To facilitate the compliance with current regulations regarding the traceability , each device is accompanied by identification product labels indicating the code and batch number, which will be pasted on the medical history related to the patient and archived by doctor and on the present “Dental implant passport”, which will be given to you, so in the future any dentist will be able to identify your implant situation.

Research and design

For many years professionals have used and still use in daily practice different type of implant systems with different forms and connections.

What we have put under the microscope were the results published in specialized magazines, reports from national and world congresses, training evenings at professional studies and more , which have directed us in the selection of a product surrounded by successes.

Having completed the product analysis we have focused on its development and manufacture, because the quality and precision become the main objectives due to very delicate application of product and they become possible thanks to the use of precision equipment managed by specialized personnel.

Guarantee

To ensure the warranty conditions, follow-up visits should be completed for 3 years after surgery.

Material and osseointegration

by Shild Biomedik GmbH makes its devices of titanium because its chemical-physical characteristics make it the best candidate for the manufacturing of implant systems; no intolerance from human body against it were ever observed and it has no toxicity.

The titanium used for implants manufacture complies with regulation ASTM F-67 (American Society for Testing and Materials) and complies with regulation ASTM F-136 for prosthetic components manufacture.

The intraoral implants are made of GRADE 4 pure titanium 99.9%, which surface in presence of oxygen forms titanium dioxide, that is the best biocompatible and therefore osseointegrable form. Osseointegration means that the intraoral implant, when the healing is completed a few week later after the bone surgery, is entirely and closely wrapped in bone tissue and no other tissue is present (connective or epithelial for example).

The bone tissue that interpenetrates the implant surface, which is roughened specifically so that the cells and trabeculae of bone can find a multitude of ravines where they can enter, is not a bone formed only by inert trabeculae, but, as all bone tissues of body, it is an alive and extremely biologically active structure.

According to by Shild Biomedik GmbH manufacture processing, so called Aluminium Free Processing, we certified that TiSmart2 dental implant is not contaminated by Aluminium.

Patient information

The regulations in force require that the patient must be informed by doctor about risks related to the implantation of device and about possible surgical complications.

The patient must be also instructed to do the programmed checkup visits and / or in case when abnormal symptoms are present .

TiSmart2®
by Shild Biomedik GmbH

ALUMINIUM FREE PROCESSING

OUR COMPANY IS YOUR COMPANY

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