

EC DECLARATION OF CONFORMITY

We: "MSDI Medical Systems and Devices International Ltd."

Derech Haifa 37, Kiryat Ata, 2822639, P.O Box 25414, Israel.

Tel: +972-(0)54-932-0515

SRN Number: IL-MF-000033949

Declare under our sole responsibility that the following products listed in annex 1 meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and Of the Council concerning medical devices which apply to them.

The MSDI Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The product(s) is (are) intended to be used by licensed dentist, for treatment of patient in the clinic.

The devices (Dental Implants and abutments) are classified in Class IIb according to Rule no.8 of Annex VIII of the Regulation (EU) 2017/745, are described in Attachment 1.

The Conformity assessment route is Annex IX of the Regulation (EU) 2017/745 of the European Parliament. Conformity assessment is based on a quality management system and on assessment of technical documentation as well as the list of standards as described in Attachment 2.

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MeDNeT EC-REP IIb GmbH

Borkstrasse 10, 48163 Münster, Germany

SRN: DE-AR-000011192

Notified Body: mdc medical device certification GmbH

NB No. 0483

Kriegerstraße 6, 70191 Stuttgart, Germany

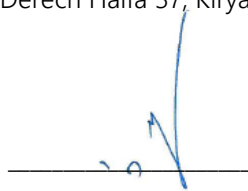
E-mail: mdc@mdc-ce.de

Registration No. D1441800006

This DOC is valid until: 2028-05-03

Date: 2024-12-16

Place of issue of the declaration: Derech Haifa 37, Kiryat Ata, Israel.



Omri Elgerabli, CEO



Basic UDI-DI for Implants: 7290018434IMP7S

Basic UDI-DI for Abutments: 7290018434ABT5R

Attachment 1: List of Product

Cat. No	Description	Provision state	Basic UDI-DI
AL3508	ALEF 3.5x8	Sterile	7290018434IMP7S
AL3510	ALEF 3.5x10	Sterile	7290018434IMP7S
AL3511	ALEF 3.5x11.5	Sterile	7290018434IMP7S
AL3513	ALEF 3.5x13	Sterile	7290018434IMP7S
AL3516	ALEF 3.5x16	Sterile	7290018434IMP7S
AL3708	ALEF 3.75x8	Sterile	7290018434IMP7S
AL3710	ALEF 3.75x10	Sterile	7290018434IMP7S
AL3711	ALEF 3.75x11.5	Sterile	7290018434IMP7S
AL3713	ALEF 3.75x13	Sterile	7290018434IMP7S
AL3716	ALEF 3.75x16	Sterile	7290018434IMP7S
AL4206	ALEF 4.2x6	Sterile	7290018434IMP7S
AL4208	ALEF 4.2x8	Sterile	7290018434IMP7S
AL4210	ALEF 4.2x10	Sterile	7290018434IMP7S
AL4211	ALEF 4.2x11.5	Sterile	7290018434IMP7S
AL4213	ALEF 4.2x13	Sterile	7290018434IMP7S
AL4216	ALEF 4.2x16	Sterile	7290018434IMP7S
AL5006	ALEF 5x6	Sterile	7290018434IMP7S
AL5008	ALEF 5x8	Sterile	7290018434IMP7S
AL5010	ALEF 5x10	Sterile	7290018434IMP7S
AL5011	ALEF 5x11.5	Sterile	7290018434IMP7S
AL5013	ALEF 5x13	Sterile	7290018434IMP7S
AL5016	ALEF 5x16	Sterile	7290018434IMP7S
AL6006	ALEF 6x6	Sterile	7290018434IMP7S
AL6008	ALEF 6x8	Sterile	7290018434IMP7S
AL6010	ALEF 6x10	Sterile	7290018434IMP7S
AL6011	ALEF 6x11.5	Sterile	7290018434IMP7S
AL6013	ALEF 6x13	Sterile	7290018434IMP7S
CX3508	CONIX 3.5x8	Sterile	7290018434IMP7S
CX3510	CONIX 3.5x10	Sterile	7290018434IMP7S
CX3511	CONIX 3.5x11.5	Sterile	7290018434IMP7S
CX3513	CONIX 3.5x13	Sterile	7290018434IMP7S
CX3516	CONIX 3.5x16	Sterile	7290018434IMP7S
CX4308	CONIX 4.3x8	Sterile	7290018434IMP7S
CX4310	CONIX 4.3x10	Sterile	7290018434IMP7S
CX4311	CONIX 4.3x11.5	Sterile	7290018434IMP7S
CX4313	CONIX 4.3x13	Sterile	7290018434IMP7S
CX4316	CONIX 4.3x16	Sterile	7290018434IMP7S
CX5008	CONIX 5x8	Sterile	7290018434IMP7S
CX5010	CONIX 5x10	Sterile	7290018434IMP7S
CX5011	CONIX 5x11.5	Sterile	7290018434IMP7S



Cat. No	Description	Provision state	Basic UDI-DI
CX5013	CONIX 5x13	Sterile	7290018434IMP7S
CX5016	CONIX 5x16	Sterile	7290018434IMP7S
TL3008	TIL 3.0x8	Sterile	7290018434IMP7S
TL3010	TIL 3.0x10	Sterile	7290018434IMP7S
TL3011	TIL 3.0x11.5	Sterile	7290018434IMP7S
TL3013	TIL 3.0x13	Sterile	7290018434IMP7S
TL3016	TIL 3.0x16	Sterile	7290018434IMP7S
TIL3308	TIL 3.3x8	Sterile	7290018434IMP7S
TL3310	TIL 3.3x10	Sterile	7290018434IMP7S
TL3311	TIL 3.3x11.5	Sterile	7290018434IMP7S
TL3313	TIL 3.3x13	Sterile	7290018434IMP7S
TL3316	TIL 3.3x16	Sterile	7290018434IMP7S
AHC2	Anatomic healing abutment 2	Non- sterile	7290018434ABT5R
AHC3	Anatomic healing abutment 3	Non- sterile	7290018434ABT5R
AHC4	Anatomic healing abutment 4	Non- sterile	7290018434ABT5R
AHC5	Anatomic healing abutment 5	Non- sterile	7290018434ABT5R
AHC6	Anatomic healing abutment 6	Non- sterile	7290018434ABT5R
AHCW2	Anatomic healing abutment wide 2	Non- sterile	7290018434ABT5R
AHCW3	Anatomic healing abutment wide 3	Non- sterile	7290018434ABT5R
AHCW4	Anatomic healing abutment wide 4	Non- sterile	7290018434ABT5R
AHCW5	Anatomic healing abutment wide 5	Non- sterile	7290018434ABT5R
AHCW6	Anatomic healing abutment wide 6	Non- sterile	7290018434ABT5R
HC2	Healing abutment 2mm	Non- sterile	7290018434ABT5R
HC3	Healing abutment 3mm	Non- sterile	7290018434ABT5R
HC4	Healing abutment 4mm	Non- sterile	7290018434ABT5R
HC5	Healing abutment 5mm	Non- sterile	7290018434ABT5R
HC6	Healing abutment 6mm	Non- sterile	7290018434ABT5R
HC7	Healing abutment 7mm	Non- sterile	7290018434ABT5R
HCW2	Healing abutment wide 2mm	Non- sterile	7290018434ABT5R
HCW3	Healing abutment wide 3mm	Non- sterile	7290018434ABT5R
HCW4	Healing abutment wide 4mm	Non- sterile	7290018434ABT5R
HCW5	Healing abutment wide 5mm	Non- sterile	7290018434ABT5R
HCW6	Healing abutment wide 6mm	Non- sterile	7290018434ABT5R
HCN2	Healing abutment narrow 2mm	Non- sterile	7290018434ABT5R
HCN3	Healing abutment narrow 3mm	Non- sterile	7290018434ABT5R
HCN4	Healing abutment narrow 4mm	Non- sterile	7290018434ABT5R
HCN5	Healing abutment narrow 5mm	Non- sterile	7290018434ABT5R
HCN6	Healing abutment narrow 6mm	Non- sterile	7290018434ABT5R
HCN7	Healing abutment narrow 7mm	Non- sterile	7290018434ABT5R
SAN5	Straight abutment narrow 5mm	Non- sterile	7290018434ABT5R
SAN7	Straight abutment narrow 7mm	Non- sterile	7290018434ABT5R
SAN9	Straight abutment narrow 9mm	Non- sterile	7290018434ABT5R
SA5	Straight abutment 5mm	Non- sterile	7290018434ABT5R
SA7	Straight abutment 7mm	Non- sterile	7290018434ABT5R
SA9	Straight abutment 9mm	Non- sterile	7290018434ABT5R
SA11	Straight abutment 11mm	Non- sterile	7290018434ABT5R
SA1	Straight abutment with shoulder 1mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
SA2	Straight abutment with shoulder 2mm	Non- sterile	7290018434ABT5R
SA3	Straight abutment with shoulder 3mm	Non- sterile	7290018434ABT5R
SA4	Straight abutment with shoulder 4mm	Non- sterile	7290018434ABT5R
SAW9	Straight abutment wide 9 mm	Non- sterile	7290018434ABT5R
SAW11	Straight abutment wide 11 mm	Non- sterile	7290018434ABT5R
SAW1	Straight abutment wide with shoulder 1mm	Non- sterile	7290018434ABT5R
SAW2	Straight abutment wide with shoulder 2mm	Non- sterile	7290018434ABT5R
SAW3	Straight abutment wide with shoulder 3mm	Non- sterile	7290018434ABT5R
SAW4	Straight abutment wide with shoulder 4mm	Non- sterile	7290018434ABT5R
ASA1	Anatomic straight abutment with shoulder 1	Non- sterile	7290018434ABT5R
ASA2	Anatomic straight abutment with shoulder 2	Non- sterile	7290018434ABT5R
ASA3	Anatomic straight abutment with shoulder 3	Non- sterile	7290018434ABT5R
ASA4	Anatomic straight abutment with shoulder 4	Non- sterile	7290018434ABT5R
TAR	Temporary abutment rotational	Non- sterile	7290018434ABT5R
TANR	Temporary abutment non rotational	Non- sterile	7290018434ABT5R
AA15	Angled abutment 15° 9mm	Non- sterile	7290018434ABT5R
AA15L	Angled abutment 15° 11mm	Non- sterile	7290018434ABT5R
AA25	Angled abutment 25° 9mm	Non- sterile	7290018434ABT5R
AA25L	Angled abutment 25° 11mm	Non- sterile	7290018434ABT5R
AA151	Angled abutment 15° with shoulder 1mm	Non- sterile	7290018434ABT5R
AA152	Angled abutment 15° with shoulder 2mm	Non- sterile	7290018434ABT5R
AA153	Angled abutment 15° with shoulder 3mm	Non- sterile	7290018434ABT5R
AA154	Angled abutment 15° with shoulder 4mm	Non- sterile	7290018434ABT5R
AA251	Angled abutment 25° with shoulder 1mm	Non- sterile	7290018434ABT5R
AA252	Angled abutment 25° with shoulder 2mm	Non- sterile	7290018434ABT5R
AA253	Angled abutment 25° with shoulder 3mm	Non- sterile	7290018434ABT5R
AA254	Angled abutment 25° with shoulder 4mm	Non- sterile	7290018434ABT5R
AAA151	Anatomic Angled abutment 15° with shoulder 1mm	Non- sterile	7290018434ABT5R
AAA152	Anatomic Angled abutment 15° with shoulder 2mm	Non- sterile	7290018434ABT5R
AAA153	Anatomic Angled abutment 15° with shoulder 3mm	Non- sterile	7290018434ABT5R
AAA251	Anatomic Angled abutment 25° with shoulder 1mm	Non- sterile	7290018434ABT5R
AAA252	Anatomic Angled abutment 25° with shoulder 2mm	Non- sterile	7290018434ABT5R
AAA253	Anatomic Angled abutment 25° with shoulder 3mm	Non- sterile	7290018434ABT5R
BA1	Ball attachment 1mm	Non- sterile	7290018434ABT5R
BA2	Ball attachment 2mm	Non- sterile	7290018434ABT5R
BA3	Ball attachment 3mm	Non- sterile	7290018434ABT5R
BA4	Ball attachment 4mm	Non- sterile	7290018434ABT5R
BA5	Ball attachment 5mm	Non- sterile	7290018434ABT5R
BA6	Ball attachment 6mm	Non- sterile	7290018434ABT5R
BA7	Ball attachment 7mm	Non- sterile	7290018434ABT5R
BAKIT1	Ball attachment kit 1mm	Non- sterile	7290018434ABT5R
BAKIT2	Ball attachment kit 2mm	Non- sterile	7290018434ABT5R
BAKIT3	Ball attachment kit 3mm	Non- sterile	7290018434ABT5R
BAKIT4	Ball attachment kit 4mm	Non- sterile	7290018434ABT5R
BAKIT5	Ball attachment kit 5mm	Non- sterile	7290018434ABT5R
BAKIT6	Ball attachment kit 6mm	Non- sterile	7290018434ABT5R
BAKIT7	Ball attachment kit 7mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
LOCK05	Lock attachment 0.5mm	Non- sterile	7290018434ABT5R
LOCK1	Lock attachment 1mm	Non- sterile	7290018434ABT5R
LOCK2	Lock attachment 2mm	Non- sterile	7290018434ABT5R
LOCK3	Lock attachment 3mm	Non- sterile	7290018434ABT5R
LOCK4	Lock attachment 4mm	Non- sterile	7290018434ABT5R
LOCK5	Lock attachment 5mm	Non- sterile	7290018434ABT5R
LOCK6	Lock attachment 6mm	Non- sterile	7290018434ABT5R
LKIT05	Lock attachment kit 0.5mm	Non- sterile	7290018434ABT5R
LKIT1	Lock attachment kit 1mm	Non- sterile	7290018434ABT5R
LKIT2	Lock attachment kit 2mm	Non- sterile	7290018434ABT5R
LKIT3	Lock attachment kit 3mm	Non- sterile	7290018434ABT5R
LKIT4	Lock attachment kit 4mm	Non- sterile	7290018434ABT5R
LKIT5	Lock attachment kit 5mm	Non- sterile	7290018434ABT5R
LKIT6	Lock attachment kit 6mm	Non- sterile	7290018434ABT5R
ALOCK181	Angled Lock attachment 18° 1mm	Non- sterile	7290018434ABT5R
ALOCK182	Angled Lock attachment 18° 2mm	Non- sterile	7290018434ABT5R
ALOCK183	Angled Lock attachment 18° 3mm	Non- sterile	7290018434ABT5R
ALOCK301	Angled Lock attachment 30° 1mm	Non- sterile	7290018434ABT5R
ALOCK302	Angled Lock attachment 30° 2mm	Non- sterile	7290018434ABT5R
ALOCK303	Angled Lock attachment 30° 3mm	Non- sterile	7290018434ABT5R
ALKIT181	Angled Lock attachment kit 18° 1mm	Non- sterile	7290018434ABT5R
ALKIT182	Angled Lock attachment kit 18° 2mm	Non- sterile	7290018434ABT5R
ALKIT183	Angled Lock attachment kit 18° 3mm	Non- sterile	7290018434ABT5R
ALKIT301	Angled Lock attachment kit 30° 1mm	Non- sterile	7290018434ABT5R
ALKIT302	Angled Lock attachment kit 30° 2mm	Non- sterile	7290018434ABT5R
ALKIT303	Angled Lock attachment kit 30° 3mm	Non- sterile	7290018434ABT5R
MUA1	Multi-unit straight abutment 1mm	Non- sterile	7290018434ABT5R
MUA2	Multi-unit straight abutment 2mm	Non- sterile	7290018434ABT5R
MUA3	Multi-unit straight abutment 3mm	Non- sterile	7290018434ABT5R
MUA4	Multi-unit straight abutment 4mm	Non- sterile	7290018434ABT5R
MUA5	Multi-unit straight abutment 5mm	Non- sterile	7290018434ABT5R
MUKIT1	Multi-unit straight kit 1mm	Non- sterile	7290018434ABT5R
MUKIT2	Multi-unit straight kit 2mm	Non- sterile	7290018434ABT5R
MUKIT3	Multi-unit straight kit 3mm	Non- sterile	7290018434ABT5R
MUKIT4	Multi-unit straight kit 4mm	Non- sterile	7290018434ABT5R
MUKIT5	Multi-unit straight kit 5mm	Non- sterile	7290018434ABT5R
MUHC	Multi-unit healing cap	Non- sterile	7290018434ABT5R
MUA171	Multi-unit angled abutment 17° 1mm	Non- sterile	7290018434ABT5R
MUA172	Multi-unit angled abutment 17° 2mm	Non- sterile	7290018434ABT5R
MUA173	Multi-unit angled abutment 17° 3mm	Non- sterile	7290018434ABT5R
MUA174	Multi-unit angled abutment 17° 4mm	Non- sterile	7290018434ABT5R
MUA301	Multi-unit angled abutment 30° 1mm	Non- sterile	7290018434ABT5R
MUA302	Multi-unit angled abutment 30° 2mm	Non- sterile	7290018434ABT5R
MUA303	Multi-unit angled abutment 30° 3mm	Non- sterile	7290018434ABT5R
MUA304	Multi-unit angled abutment 30° 4mm	Non- sterile	7290018434ABT5R
MUA451	Multi-unit angled abutment 45° 1mm	Non- sterile	7290018434ABT5R
MUA452	Multi-unit angled abutment 45° 2mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
MUA453	Multi-unit angled abutment 45° 3mm	Non- sterile	7290018434ABT5R
MUAKIT454	Multi-unit angled abutment kit 45° 4mm	Non- sterile	7290018434ABT5R
MUKIT171	Multi-unit angled kit 17° 1mm	Non- sterile	7290018434ABT5R
MUKIT172	Multi-unit angled kit 17° 2mm	Non- sterile	7290018434ABT5R
MUKIT173	Multi-unit angled kit 17° 3mm	Non- sterile	7290018434ABT5R
MUKIT174	Multi-unit angled kit 17° 4mm	Non- sterile	7290018434ABT5R
MUKIT301	Multi-unit angled kit 30° 1mm	Non- sterile	7290018434ABT5R
MUKIT302	Multi-unit angled kit 30° 2mm	Non- sterile	7290018434ABT5R
MUKIT303	Multi-unit angled kit 30° 3mm	Non- sterile	7290018434ABT5R
MUKIT304	Multi-unit angled kit 30° 4mm	Non- sterile	7290018434ABT5R
MUKIT451	Multi-unit angled kit 45° 1mm	Non- sterile	7290018434ABT5R
MUKIT452	Multi-unit angled kit 45° 2mm	Non- sterile	7290018434ABT5R
MUKIT453	Multi-unit angled kit 45° 3mm	Non- sterile	7290018434ABT5R
TBNR00	Ti base abutment non rotational 0mm	Non- sterile	7290018434ABT5R
TBNR05	Ti base abutment non rotational 0.5mm	Non- sterile	7290018434ABT5R
TBNR15	Ti base abutment non rotational 1.5mm	Non- sterile	7290018434ABT5R
TBNR25	Ti base abutment non rotational 2.5mm	Non- sterile	7290018434ABT5R
TBR05	Ti base abutment rotational 0.5mm	Non- sterile	7290018434ABT5R
TBR15	Ti base abutment rotational 1.5mm	Non- sterile	7290018434ABT5R
TBR25	Ti base abutment rotational 2.5mm	Non- sterile	7290018434ABT5R
TBNR00	Ti base abutment non rotational 0mm	Non- sterile	7290018434ABT5R
TBNR35	Ti base abutment non rotational 3.5mm	Non- sterile	7290018434ABT5R
TBNR45	Ti base abutment non rotational 4.5mm	Non- sterile	7290018434ABT5R
TBR00	Ti base abutment rotational 0mm	Non- sterile	7290018434ABT5R
TBR35	Ti base abutment rotational 3.5mm	Non- sterile	7290018434ABT5R
TBR45	Ti base abutment rotational 4.5mm	Non- sterile	7290018434ABT5R
STBR05	Sirona Compatible Ti Base rotational 0.5mm	Non- sterile	7290018434ABT5R
STBR15	Sirona Compatible Ti Base rotational 1.5mm	Non- sterile	7290018434ABT5R
STBR30	Sirona Compatible Ti Base rotational 3.0mm	Non- sterile	7290018434ABT5R
STBNR05	Sirona Compatible Ti Base non rotational 0.5mm	Non- sterile	7290018434ABT5R
STBNR15	Sirona Compatible Ti Base non rotational 1.5mm	Non- sterile	7290018434ABT5R
STBNR30	Sirona Compatible Ti Base non rotational 3.0mm	Non- sterile	7290018434ABT5R
ALCS	Cover screw	Sterile	7290018434ABT5R
RPHC2	Healing abutment RP 2mm	Non- sterile	7290018434ABT5R
RPHC3	Healing abutment RP 3mm	Non- sterile	7290018434ABT5R
RPHC4	Healing abutment RP 4mm	Non- sterile	7290018434ABT5R
RPHC5	Healing abutment RP 5mm	Non- sterile	7290018434ABT5R
RPSA1	Straight abutment RP with shoulder 1mm	Non- sterile	7290018434ABT5R
RPSA2	Straight abutment RP with shoulder 2mm	Non- sterile	7290018434ABT5R
RPSA3	Straight abutment RP with shoulder 3mm	Non- sterile	7290018434ABT5R
RPSA9	Straight abutment RP 9mm	Non- sterile	7290018434ABT5R
RPSA11	Straight abutment RP 11mm	Non- sterile	7290018434ABT5R
RPSA13	Straight abutment RP 13mm	Non- sterile	7290018434ABT5R
RPA151	Angled abutment 15° RP with shoulder 1.5mm	Non- sterile	7290018434ABT5R
RPA251	Angled abutment 25° RP with shoulder 1.5mm	Non- sterile	7290018434ABT5R
RPA153	Angled abutment 15° RP with shoulder 3.0mm	Non- sterile	7290018434ABT5R
RPA253	Angled abutment 25° RP with shoulder 3.0mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
RPTBNR05	Ti base abutment RP non rotational 0.5mm	Non- sterile	7290018434ABT5R
RPTBNR15	Ti base abutment RP non rotational 1.5mm	Non- sterile	7290018434ABT5R
RPTBNR25	Ti base abutment RP non rotational 2.5mm	Non- sterile	7290018434ABT5R
RPTBR05	Ti base abutment RP rotational 0.5mm	Non- sterile	7290018434ABT5R
RPTBR15	Ti base abutment RP rotational 1.5mm	Non- sterile	7290018434ABT5R
RPTBR25	Ti base abutment RP rotational 2.5mm	Non- sterile	7290018434ABT5R
RPMUA1	Multi-unit straight abutment RP 1mm	Non- sterile	7290018434ABT5R
RPMUA2	Multi-unit straight abutment RP 2mm	Non- sterile	7290018434ABT5R
RPMUA3	Multi-unit straight abutment RP 3mm	Non- sterile	7290018434ABT5R
RPMUA4	Multi-unit straight abutment RP 4mm	Non- sterile	7290018434ABT5R
RPMUKIT1	Multi-unit straight kit RP 1mm	Non- sterile	7290018434ABT5R
RPMUKIT2	Multi-unit straight kit RP 2mm	Non- sterile	7290018434ABT5R
RPMUKIT3	Multi-unit straight kit RP 3mm	Non- sterile	7290018434ABT5R
RPMUKIT4	Multi-unit straight kit RP 4mm	Non- sterile	7290018434ABT5R
RPMUA171	Multi-unit Angled abutment 17° RP 1mm	Non- sterile	7290018434ABT5R
RPMUA172	Multi-unit Angled abutment 17° RP 2mm	Non- sterile	7290018434ABT5R
RPMUA301	Multi-unit Angled abutment 30° RP 1mm	Non- sterile	7290018434ABT5R
RPMUA302	Multi-unit Angled abutment 30° RP 2mm	Non- sterile	7290018434ABT5R
RPMUKIT171	Multi-unit angled kit 17° RP 1mm	Non- sterile	7290018434ABT5R
RPMUKIT172	Multi-unit angled kit 17° RP 2mm	Non- sterile	7290018434ABT5R
RPMUKIT301	Multi-unit angled kit 30° RP 1mm	Non- sterile	7290018434ABT5R
RPMUKIT302	Multi-unit angled kit 30° RP 2mm	Non- sterile	7290018434ABT5R
RPBA1	Ball attachment RP 1mm	Non- sterile	7290018434ABT5R
RPBA2	Ball attachment RP 2mm	Non- sterile	7290018434ABT5R
RPBA3	Ball attachment RP 3mm	Non- sterile	7290018434ABT5R
RPBA4	Ball attachment RP 4mm	Non- sterile	7290018434ABT5R
RPBA5	Ball attachment RP 5mm	Non- sterile	7290018434ABT5R
RPBAKIT1	Ball attachment kit RP 1mm	Non- sterile	7290018434ABT5R
RPBAKIT2	Ball attachment kit RP 2mm	Non- sterile	7290018434ABT5R
RPBAKIT3	Ball attachment kit RP 3mm	Non- sterile	7290018434ABT5R
RPBAKIT4	Ball attachment kit RP 4mm	Non- sterile	7290018434ABT5R
RPBAKIT5	Ball attachment kit RP 5mm	Non- sterile	7290018434ABT5R
RPLOCK1	Lock attachment RP 1mm	Non- sterile	7290018434ABT5R
RPLOCK2	Lock attachment RP 2mm	Non- sterile	7290018434ABT5R
RPLOCK3	Lock attachment RP 3mm	Non- sterile	7290018434ABT5R
RPLOCK4	Lock attachment RP 4mm	Non- sterile	7290018434ABT5R
RPLKIT1	Lock attachment kit RP 1mm	Non- sterile	7290018434ABT5R
RPLKIT2	Lock attachment kit RP 2mm	Non- sterile	7290018434ABT5R
RPLKIT3	Lock attachment kit RP 3mm	Non- sterile	7290018434ABT5R
RPLKIT4	Lock attachment kit RP 4mm	Non- sterile	7290018434ABT5R
NPHC2	Healing abutment NP 2mm	Non- sterile	7290018434ABT5R
NPHC3	Healing abutment NP 3mm	Non- sterile	7290018434ABT5R
NPHC4	Healing abutment NP 4mm	Non- sterile	7290018434ABT5R
NPHC5	Healing abutment NP 5mm	Non- sterile	7290018434ABT5R
NPSA1	Straight abutment NP with shoulder 1mm	Non- sterile	7290018434ABT5R
NPSA2	Straight abutment NP with shoulder 2mm	Non- sterile	7290018434ABT5R
NPSA3	Straight abutment NP with shoulder 3mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
NPSA9	Straight abutment NP 9mm	Non- sterile	7290018434ABT5R
NPSA11	Straight abutment NP 11mm	Non- sterile	7290018434ABT5R
NPSA13	Straight abutment NP 13mm	Non- sterile	7290018434ABT5R
NPA151	Angled abutment 15° NP with shoulder 1.5mm	Non- sterile	7290018434ABT5R
NPA251	Angled abutment 25° NP with shoulder 1.5mm	Non- sterile	7290018434ABT5R
NPA153	Angled abutment 15° NP with shoulder 3.0mm	Non- sterile	7290018434ABT5R
NPA253	Angled abutment 25° NP with shoulder 3.0mm	Non- sterile	7290018434ABT5R
NPTBNR05	Ti base abutment NP non rotational 0.5mm	Non- sterile	7290018434ABT5R
NPTBNR15	Ti base abutment NP non rotational 1.5mm	Non- sterile	7290018434ABT5R
NPTBNR25	Ti base abutment NP non rotational 2.5mm	Non- sterile	7290018434ABT5R
NPTBR05	Ti base abutment NP rotational 0.5	Non- sterile	7290018434ABT5R
NPTBR15	Ti base abutment NP rotational 1.5mm	Non- sterile	7290018434ABT5R
NPTBR25	Ti base abutment NP rotational 2.5mm	Non- sterile	7290018434ABT5R
NPMUA1	Multi-unit straight abutment NP 1mm	Non- sterile	7290018434ABT5R
NPMUA2	Multi-unit straight abutment NP 2mm	Non- sterile	7290018434ABT5R
NPMUA3	Multi-unit straight abutment NP 3mm	Non- sterile	7290018434ABT5R
NPMUA4	Multi-unit straight abutment NP 4mm	Non- sterile	7290018434ABT5R
NPMUKIT1	Multi-unit straight kit NP 1mm	Non- sterile	7290018434ABT5R
NPMUKIT2	Multi-unit straight kit NP 2mm	Non- sterile	7290018434ABT5R
NPMUKIT3	Multi-unit straight kit NP 3mm	Non- sterile	7290018434ABT5R
NPMUKIT4	Multi-unit straight kit NP 4mm	Non- sterile	7290018434ABT5R
NPMUA171	Multi-unit Angled abutment 17° NP 1mm	Non- sterile	7290018434ABT5R
NPMUA172	Multi-unit Angled abutment 17° NP 2mm	Non- sterile	7290018434ABT5R
NPMUA301	Multi-unit Angled abutment 30° NP 1mm	Non- sterile	7290018434ABT5R
NPMUA302	Multi-unit Angled abutment 30° NP 2mm	Non- sterile	7290018434ABT5R
NPMUKIT171	Multi-unit angled kit 17° NP 1mm	Non- sterile	7290018434ABT5R
NPMUKIT172	Multi-unit angled kit 17° NP 2mm	Non- sterile	7290018434ABT5R
NPMUKIT301	Multi-unit angled kit 30° NP 1mm	Non- sterile	7290018434ABT5R
NPMUKIT302	Multi-unit angled kit 30° NP 2mm	Non- sterile	7290018434ABT5R
NPBA1	Ball attachment NP 1mm	Non- sterile	7290018434ABT5R
NPBA2	Ball attachment NP 2mm	Non- sterile	7290018434ABT5R
NPBA3	Ball attachment NP 3mm	Non- sterile	7290018434ABT5R
NPBA4	Ball attachment NP 4mm	Non- sterile	7290018434ABT5R
NPBA5	Ball attachment NP 5mm	Non- sterile	7290018434ABT5R
NPBAKIT1	Ball attachment kit NP 1mm	Non- sterile	7290018434ABT5R
NPBAKIT2	Ball attachment kit NP 2mm	Non- sterile	7290018434ABT5R
NPBAKIT3	Ball attachment kit NP 3mm	Non- sterile	7290018434ABT5R
NPBAKIT4	Ball attachment kit NP 4mm	Non- sterile	7290018434ABT5R
NPBAKIT5	Ball attachment kit NP 5mm	Non- sterile	7290018434ABT5R
NPLOCK1	Lock attachment NP 1mm	Non- sterile	7290018434ABT5R
NPLOCK2	Lock attachment NP2mm	Non- sterile	7290018434ABT5R
NPLOCK3	Lock attachment NP 3mm	Non- sterile	7290018434ABT5R
NPLOCK4	Lock attachment NP 4mm	Non- sterile	7290018434ABT5R
NPLKIT1	Lock attachment kit NP 1mm	Non- sterile	7290018434ABT5R
NPLKIT2	Lock attachment kit NP 2mm	Non- sterile	7290018434ABT5R
NPLKIT3	Lock attachment kit NP 3mm	Non- sterile	7290018434ABT5R
NPLKIT4	Lock attachment kit NP 4mm	Non- sterile	7290018434ABT5R



Cat. No	Description	Provision state	Basic UDI-DI
RPCS	Cover screw RP	Sterile	7290018434ABT5R
NPCS	Cover screw NP	Sterile	7290018434ABT5R
TPHC2	Healing abutment TP 2mm	Non- sterile	7290018434ABT5R
TPHC3	Healing abutment TP 3mm	Non- sterile	7290018434ABT5R
TPHC4	Healing abutment TP 4mm	Non- sterile	7290018434ABT5R
TPHC5	Healing abutment TP 5mm	Non- sterile	7290018434ABT5R
TPHC6	Healing abutment TP 6mm	Non- sterile	7290018434ABT5R
TPSA1	Straight abutment TP with shoulder 1mm	Non- sterile	7290018434ABT5R
TPSA2	Straight abutment TP with shoulder 2mm	Non- sterile	7290018434ABT5R
TPSA3	Straight abutment TP with shoulder 3mm	Non- sterile	7290018434ABT5R
TPSA4	Straight abutment TP with shoulder 4mm	Non- sterile	7290018434ABT5R
TPSA9	Straight abutment TP 9mm	Non- sterile	7290018434ABT5R
TPA15	Angled abutment 15° TP	Non- sterile	7290018434ABT5R
TPCATB	Castable abutment with titanium base TP	Non- sterile	7290018434ABT5R
TPBA1	Ball attachment TP 1mm	Non- sterile	7290018434ABT5R
TPBA2	Ball attachment TP 2mm	Non- sterile	7290018434ABT5R
TPBA3	Ball attachment TP 3mm	Non- sterile	7290018434ABT5R
TPBA4	Ball attachment TP 4mm	Non- sterile	7290018434ABT5R
TPBA5	Ball attachment TP 5mm	Non- sterile	7290018434ABT5R
TPBA6	Ball attachment TP 6mm	Non- sterile	7290018434ABT5R
TPBAKIT1	Ball attachment kit TP 1mm	Non- sterile	7290018434ABT5R
TPBAKIT2	Ball attachment kit TP 2mm	Non- sterile	7290018434ABT5R
TPBAKIT3	Ball attachment kit TP 3mm	Non- sterile	7290018434ABT5R
TPBAKIT4	Ball attachment kit TP 4mm	Non- sterile	7290018434ABT5R
TPBAKIT5	Ball attachment kit TP 5mm	Non- sterile	7290018434ABT5R
TPBAKIT6	Ball attachment kit TP 6mm	Non- sterile	7290018434ABT5R
TPLOCK05	Lock attachment TP 0.5mm	Non- sterile	7290018434ABT5R
TPLOCK1	Lock attachment TP 1mm	Non- sterile	7290018434ABT5R
TPLOCK2	Lock attachment TP 2mm	Non- sterile	7290018434ABT5R
TPLOCK3	Lock attachment TP 3mm	Non- sterile	7290018434ABT5R
TPLOCK4	Lock attachment TP 4mm	Non- sterile	7290018434ABT5R
TPLOCK5	Lock attachment TP 5mm	Non- sterile	7290018434ABT5R
TPLOCK6	Lock attachment TP 6mm	Non- sterile	7290018434ABT5R
TPLKIT05	Lock attachment kit TP 0.5mm	Non- sterile	7290018434ABT5R
TPLKIT1	Lock attachment kit TP 1mm	Non- sterile	7290018434ABT5R
TPLKIT2	Lock attachment kit TP 2mm	Non- sterile	7290018434ABT5R
TPLKIT3	Lock attachment kit TP 3mm	Non- sterile	7290018434ABT5R
TPLKIT4	Lock attachment kit TP 4mm	Non- sterile	7290018434ABT5R
TPLKIT5	Lock attachment kit TP 5mm	Non- sterile	7290018434ABT5R
TPLKIT6	Lock attachment kit TP 6mm	Non- sterile	7290018434ABT5R
TPCS	Cover screw TP	Sterile	7290018434ABT5R
TPMUA1	Multi-unit straight abutment TP 1mm	Non- sterile	7290018434ABT5R
TPMUA2	Multi-unit straight abutment TP 2mm	Non- sterile	7290018434ABT5R
TPMUA3	Multi unit straight abutment TP 3mm	Non- sterile	7290018434ABT5R
TPMUA4	Multi unit straight abutment TP 4mm	Non- sterile	7290018434ABT5R
TPMUA5	Multi unit straight abutment TP 5mm	Non- sterile	7290018434ABT5R

Cat. No	Description	Provision state	Basic UDI-DI
TPMUKIT1	Multi-unit straight kit TP 1mm	Non- sterile	7290018434ABT5R
TPMUKIT2	Multi-unit straight kit TP 2mm	Non- sterile	7290018434ABT5R
TPMUKIT3	Multi-unit straight kit TP 3mm	Non- sterile	7290018434ABT5R
TPMUKIT4	Multi-unit straight kit TP 4mm	Non- sterile	7290018434ABT5R
TPMUKIT5	Multi-unit straight kit TP 5mm	Non- sterile	7290018434ABT5R
TPMUA171	Multi unit angled abutment TP 17° 1mm	Non- sterile	7290018434ABT5R
TPMUA172	Multi unit angled abutment TP 17° 2mm	Non- sterile	7290018434ABT5R
TPMUA301	Multi unit angled abutment TP 30° 1mm	Non- sterile	7290018434ABT5R
TPMUA302	Multi unit angled abutment TP 30° 2mm	Non- sterile	7290018434ABT5R
TPMUKIT171	Multi-unit angled kit 17° TP 1mm	Non- sterile	7290018434ABT5R
TPMUKIT172	Multi-unit angled kit 17° TP 2mm	Non- sterile	7290018434ABT5R
TPMUKIT301	Multi-unit angled kit 30° TP 1mm	Non- sterile	7290018434ABT5R
TPMUKIT302	Multi-unit angled kit 30° TP 2mm	Non- sterile	7290018434ABT5R
TPTBNR05	Ti base abutment TP non rotational 0.5mm	Non- sterile	7290018434ABT5R
TPTBNR15	Ti base abutment TP non rotational 1.5mm	Non- sterile	7290018434ABT5R
TPTBNR25	Ti base abutment TP non rotational 2.5mm	Non- sterile	7290018434ABT5R
TPTBR05	Ti base abutment TP rotational 0.5mm	Non- sterile	7290018434ABT5R
TPTBR15	Ti base abutment TP rotational 1.5mm	Non- sterile	7290018434ABT5R
TPTBR25	Ti base abutment TP rotational 2.5mm	Non- sterile	7290018434ABT5R

Attachment 2: List of Applicable Standards

#	Standard number	Standard description	Reference No. of the harmonized standard - MDR 2017/745/ BS EN adopted
1.	EU MDR 2017/745	Medical Devices Regulation (MDR) (EU) 2017/745	EN ISO 13485:2016/A11:2021
2.	ISO 13485:2016	Quality Systems-Medical Devices-System requirements for regulatory purposes	EN ISO 13485:2016/A11:2021
3.	TGA Regulation	Australian Regulatory Guidelines for Medical Devices (ARGMD)	N/A
4.	ISO 10993-1:2018	Biological evaluation of medical devices. Part 1: Evaluation and testing	BS EN ISO 10993-1:2020
5.	ISO 14971:2019	Medical Devices-Application of risk management to medical devices within a risk management process	BS EN ISO 14971:2019/A11:2021
6.	ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied	EN ISO 15223-1:2021
7.	ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer	BS EN ISO 20417:2021
8.	ISO 11607-1:2019+A1:2023	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	BS EN ISO 11607-1:2020+A1:2023
9.	ISO 11607-2:2019+A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	BS EN ISO 11607-1:2020+A1:2023
10.	ASTM F1980–2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	N/A
11.	ASTM F1929-2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	N/A
12.	ANSI/AAMI/ISO TIR 13004:2013 (R2016)	Sterilization of health care products -- Radiation -- Substantiation of selected sterilization dose: Method V _{DmaxSD}	N/A
13.	ISO 11137-1:2006/Amd 2:2018	Sterilization of health care products - radiation - Part1: Requirement for development, validation and routine control of a sterilization process for medical devices	BS EN ISO 11137-1:2015+A2:2019
14.	ISO 11137-2:2013/Amd 1:2022	Sterilization of health care products- radiation - Part2: Establishing the sterilization dose	BS EN ISO 11137-2:2015+A1:2023
15.	ISO 11137-3:2017	Sterilization of health care products- radiation – Part3: Guidance on dosimetric aspects	BS EN ISO 11137-3:2017

#	Standard number	Standard description	Reference No. of the harmonized standard - MDR 2017/745/ BS EN adopted
16.	ASTM F 136-13 (2021)	Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (extra low interstitial) alloy for surgical implant applications (UNS R56401)	N/A
17.	ISO 14801:2016	Dentistry. Implants. Dynamic fatigue test for endosseous dental implants	BS EN ISO 14801:2016
18.	ISO 5832-3:2021	Implants for surgery – Metallic materials – Wrought titanium 6-aluminium 4-vanadium alloy	BS EN ISO 5832-3:2021
19.	ISO 17665:2024	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	BS EN ISO 17665:2024
20.	ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices	BS EN ISO 17664-1:2021
21.	ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control, Part 1: General principles and methods	BS EN ISO 14698-1:2003
22.	BS EN 17141:2020	Cleanrooms and associated controlled environments. Bio contamination control	N/A
23.	ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	BS EN ISO 14644-1:2015
24.	ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	BS EN ISO 14644-2:2015
25.	ISO 14644-3:2019	Cleanrooms and associated controlled environments. Test methods	BS EN ISO 14644-3:2019
26.	ISO 14644-5:2004	Cleanrooms and associated controlled environments. Operations	BS EN ISO 14644-5:2004
27.	EU GMP Annex 1-2022	The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use	N/A
28.	ISO 11737-1:2018+A1 2021	Sterilization of medical devices - Microbiological methods - Part1: Determination of a population of microorganisms on products	BS EN ISO 11737-1:2018+A1 2021
29.	ISO 11737-2:2019	Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process	BS EN ISO 11737-2:2020
30.	ISO 11137-3:2017	Sterilization of health care products- radiation – Part3: Guidance on dosimetric aspects	BS EN ISO 11137-3:2017
31.	EN 1642:2011	Dentistry. Medical devices for dentistry. Dental implants	BS EN 1642:2011
32.	EN 62366-1:2015/Amd	Medical devices - application of usability engineering to medical devices	N/A

#	Standard number	Standard description	Reference No. of the harmonized standard - MDR 2017/745/ BS EN adopted
	1:2020		
33.	ASTM D4169-24	Standard Practice for Performance Testing of Shipping Containers and Systems	N/A
34.	ASTM D5276-23	Standard Test Method for Drop Test of Loaded Containers by Free Fall	N/A
35.	ASTM D642-20	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads	N/A
36.	ASTM D4728: 17 (2022)	Standard Test Method for Random Vibration Testing of Shipping Containers	N/A
37.	ASTM D999-08 (2015) 2023	Standard Test Methods for Vibration Testing of Shipping Containers	N/A
38.	ASTM D4332-22	Standard Practice For Conditioning Containers, Packages, Or Packaging Components For Testing (Standard + Redline PDF Bundle)	N/A
39.	ASTM F1929-15 (2023)	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	N/A
40.	ASTM F3039-15(2023)	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	N/A
41.	ASTM D3078-02 (2021)	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	N/A
42.	ASTM F2338-09 (2023)	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	N/A