

Certificate of Registration



Certificate No. CE/JPN/2015/07/76

Issued To: **Shioda Dental Co (Formally TASK, Inc)**
53 Tobara, Nasukarasuyama-shi,
Tochigi 321-0517
JAPAN

Legal Manufacturer [SRN: Not yet available]

Issued By: **Advena Limited**
Tower Business Centre, 2nd Flr, Tower
Street, Swatar, BKR 4013. Malta.

EC-REP [SRN: MT-AR-000000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life
Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with the Malta Medicines Authority (MMA) the Competent Authority of Malta.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 is legitimately permitted.

Anthony Kirby – Managing Director

Date of Issue: 26 September 2022

AR Cover Begins: 01 September 2022

AR Cover Ends: 31 August 2023

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A



Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
Dental Instruments	MDR	Class I	MT-MDF03-AA400A



Declaration of Conformity

for the Dental Instruments

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Dental Instruments
Legal Manufacturer: (Name on Label)	SHIODA DENTAL CO. 53 Tobara, Nasukarasuyama-shi, Tochigi 321-0517 JAPAN
SRN:	Not yet available.
Basic UDI-DI:	456020389TK00000YP
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Instruments to be used during dental procedures.
MDR Classification:	Class I
Notified Body:	Not applicable for class I medical devices.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Self-declaration in accordance with Article 19 after drawing up technical documentation as set out in Annexes II and III.

Name Naoto Arai **Position** Director

Signed Naoto Arai **Date** 24/09/2021 **Place** Tochigi Japan

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Appendix II – Product Listing/Schedule

Product Code	Product Name	GMDN
Dental Articulator		
47110	Articulator Flamingo C	10201
47120	Articulator Flamingo D (Pink)	10201
47128	Articulator Flamingo D (Blue)	10201
Dental mirror, reusable		
74904	Mi-4 Dental Photo Mirror Large	31776
74905	Mi-5 Dental Photo Mirror Medium	31776
74906	Mi-6 Dental Photo Mirror Small	31776
74907	Mi-7 Dental Photo Mirror Child	31776
74908	Mi-8 Dental Photo Mirror Buccal	31776
Dental collar/crown scissors		
43210	S-210 Crown Scissors (Chrome) Straight	31847
43211	S-211 Crown Scissors (Chrome) Curved	31847
43611	S-611 Crown Scissors (Chrome) Curved	31847
Wire holding/twisting pliers		
45500	Bar Bender KI Type	32874
45501	Bar Bender #1	32874
45502	Bar Bender #2	32874
45511	KI Type Bar Bending Plier #1	32874
45512	KI Type Bar Bending Plier #2	32874
Orthodontic Hand Instrument		
08275	Diamond Tweezers	33209
23215	N-215 Mathieu Needle Holder	33209
23801	N-801 Mosquito Forceps Straight	33209
23802	N-802 Mosquito Forceps Curved	33209
30566	Smaha Ligature Plier Straight (14cm)	33209
30567	Smaha Ligature Plier Curved (14cm)	33209
45020	Flat Cutter	33209
45051	Concaved Clasp Bending Plier Type I	33209
45052	Concaved Clasp Bending Plier Type II	33209

Product Code	Product Name	GMDN
Orthodontic Hand Instrument		
45074	Young Plier #74	33209
45075	Big Young Plier	33209
45110	How Plier #110	33209
45114	Johnson Plier #114	33209
45115	Reynolds Plier #115	33209
45118	Peeso Plier #118	33209
45120	Robinson Plier #120	33209
45121	Flat Nose Plier #121	33209
45122	Flat Nose Plier #122	33209
45136	Goslee Plier #136	33209
45137	Gordon Plier #137	33209
45200	Three Jaw Plier #200	33209
45201	Three Jaw Plier #200S	33209
45401	Clasp Forming Plier Type I	33209
45402	Clasp Forming Plier Type II	33209
45403	Clasp Forming Plier Type III	33209
45404	Clasp Forming Plier Type IV	33209
49404	Clasp Forming Plier KI Type	33209
49511	Concaved Clasp Bending Plier Type III	33209
49740	Young Plier #74 With Groove	33209
60015	TS-15 <TS>Pin & Ligature Cutter	33209
60020	TS-20 <TS>Weingart Utility Plier	33209
60025	TS-25 <TS> DB Bracket Removing Plier Straight	33209
60026	TS-26 <TS> DB Bracket Removing Plier Angled	33209
60030	TS-30 <TS>Posterior Band Removing Plier Long	33209
60040	60-004 Power Cutter	33209
60060	60-006 Hollow Chop Plier	33209
60090	60-009 Headgear Plier	33209
60200	P-200 <PRORTHO> Bracket Removing Plier	33209
60210	P-210 <PRORTHO> Bond Removing Plier	33209
60211	P-211 <PRORTHO> Replacement Metal Tip	33209
60220	P-220 <PRORTHO> Hook Crimping Plier	33209
60300	P-300 <PRORTHO> Lingual Utility Plier - Long Handle	33209
60400	P-400 <PRORTHO> Ligature Cutter - 40°Angle	33209
60410	P-410 <PRORTHO> Reversed Ligature Cutter - 40°Angle	33209
60420	P-420 <PRORTHO> Ligature Cutter - 50°Angle	33209
60430	P-430 <PRORTHO> Reversed Ligature Cutter - 60°Angle	33209
60500	P-500 <PRORTHO> Lingual Bracket Removing Plier	33209
60510	P-510 <PRORTHO> Lingual Bracket Removing Plier	33209
60700	P-700 <Kommon Base> Lingual Bond Removing Plier	33209
60701	P-701 <Kommon Base> Replacement Metal Tip	33209
60710	P-710 <Kommon Base> Lingual Bond Removing Plier For Front Teeth	33209
60740	60-074 Young Plier	33209
61011	60-101C Ligature Tying Plier Coon Type	33209
61020	60-102 Ligature Tying Plier	33209
61040	60-104 Posterior Band Removing Plier	33209
61041	60-104T Posterior Band Removing Plier Inserted	33209

Product Code	Product Name	GMDN
Orthodontic Hand Instrument		
61042	60-104TL Posterior Band Removing Plier Long	33209
61050	60-105 Compartible Cap Removing Plier	33209
62011	60-201L Angled Three Jaw Plier Left	33209
62012	60-201R Angled Three Jaw Plier Right	33209
62021	60-202T Quad Helix Plier	33209
62080	60-208 Band Contouring Plier	33209
62120	60-212 Crown Contouring Plier	33209
62130	60-213 Jarabak Plier	33209
62141	60-214T Adams Plier Inserted	33209
62142	60-214TR Adams Spring Forming Plier	33209
62160	60-216 Elastic Placing Plier With Hook	33209
62170	60-217 Ligating Plier	33209
62180	60-218 Elastic Placing Plier	33209
62231	60-223T Arch Forming Plier	33209
62232	60-223TG Arch Forming Plier With Grooves	33209
62241	60-224T Stop Plier	33209
62251	60-225T Ligature Forming Plier	33209
62260	60-226 Torquing Plier #M	33209
62270	60-227 Torquing Plier #F	33209
62280	60-228 Step Plier 1mm	33209
63020	60-302 Nance Closing Loop Plier	33209
63030	60-303 Tweed Arch Bending Plier	33209
63031	60-303T Tweed Arch Bending Plier Inserted	33209
63040	60-304 Tweed Loop Forming Plier	33209
63041	60-304S Omega Loop Forming Plier	33209
63042	60-304TR Tweed Loop Forming Plier	33209
63050	60-305 Loop Forming Plier	33209
63060	60-306 How Plier Regular	33209
63061	60-306T How Plier Regular, Inserted	33209
63070	60-307 How Plier Small	33209
63080	60-308 How Plier Offset	33209
63081	60-308M How Plier - Offset	33209
63090	60-309 How Plier Slim Handle	33209
63130	60-313 Three Jaw Plier	33209
63131	60-313L Heavy Three Jaw Plier	33209
63132	60-313T Three Jaw Plier Inserted	33209
63140	60-314 Bird Beak Plier	33209
63141	30-314T Bird Beak Plier Inserted	33209
63143	60-314TS Wire Bending Plier	33209
63144	60-314TL Heavy Wire Bending Plier	33209
63145	60-314TM Laboratory Plier Adams Style	33209
63150	60-315 Light Wire Plier Grooved Square Tip	33209
63151	30-315T Light Wire Plier Grooved Square Tip, Inserted	33209
63152	30-315C Light Wire Plier Grooved Square Tip With Cutter	33209
63160	60-316 Light Wire Plier	33209
63161	30-316T Light Wire Plier Inserted	33209
63162	30-316C Light Wire Plier With Cutter	33209

Product Code	Product Name	GMDN
Orthodontic Hand Instrument		
63170	60-317 Crown Crimping Plier	33209
63171	60-317S Crown Crimping Plier Slim	33209
63190	60-319 Tube Crimping Plier	33209
63200	60-320 Optical Plier	33209
63210	60-321 Lingual Arch Sheath Bending Plier	33209
63321	60-332T Bond Removing Plier	33209
63330	60-333 DBS Bracket Removing Plier	33209
63341	60-334T DB Bracket Removing Plier Angled	33209
63351	60-335T DB Bracket Removing Plier Straight	33209
64160	60-416 Begg Light Wire Plier	33209
64210	60-421 Loop Forming Plier Old Type	33209
64303	60-430CK Kim Plier With Cutter ϕ 1.3	33209
64460	60-446 Hook Crimping Plier	33209
65040	60-504 Weingart Utility Plier Small	33209
65010	60-501 Weingart Utility Plier	33209
65011	60-501T Weingart Utility Plier Inserted	33209
65020	60-502 Weigart Plier	33209
65021	30-502T Weingart Utility Plier Inserted	33209
65040	60-504 Weingart Utility Plier Small	33209
65500	30-550 Distal End Safety Hold Cutter	33209
65501	30-550S Distal End Safety Hold Cutter Slim	33209
65502	30-550SL Distal End Safety Hold Cutter Slim, Long Handle	33209
65503	30-550SF Distal End Safety Hold Cutter Flush Cut	33209
65504	30-550ES Distal End Safety Hold Cutter Slim	33209
65505	30-550FL Distal End Safety Hold Cutter Flush Cut, Long Handle	33209
65506	30-550SLS Distal End Safety Hold Cutter Slim, Long Handle Straight	33209
65507	30-551US Distal End Safety Hold Cutter Slim	33209
65508	30-550K Distal End Safety Hold Cutter	33209
65509	30-552 Distal End Safety Hold Cutter Flush Cut	33209
65510	30-553 Distal End Safety Hold Cutter Slim, Flush Cut	33209
65511	30-554 Distal End Safety Hold Cutter Slim, Flush Cut, Long Handle	33209
66040	60-604 Pin & Ligature Cutter	33209
66041	30-604W Pin & Ligature Cutter With TC Tip	33209
66042	60-604H Hard Wire Cutter	33209
66043	60-604HK Hard Wire Cutter	33209
66048	30-604WK Pin & Ligature Cutter With TC Tip	33209
66050	60-605 Pin & Ligature Cutter Miniature	33209
66051	30-605W Pin & Ligature Cutter Miniature With TC Tip	33209
66053	60-605S Pin & Ligature Cutter Slim	33209
66058	30-605WK Pin & Ligature Cutter Miniature With TC Tip	33209
66061	60-606S Pin & Ligature Cutter Slim	33209
66070	60-607 Pin & Ligature Cutter Slim - 15°Angle	33209
66200	60-620 Angular Ligature Cutter - 45°Angle	33209
67010	60-701 Elastic Separating Plier	33209
67310	60-731 Aligner Plier	33209
67320	60-732 Aligner Plier	33209
67330	60-733 Aligner Plier	33209

Product Code	Product Name	GMDN
Orthodontic Hand Instrument		
67340	60-734 Aligner Plier	33209
67350	60-735 Aligner Plier	33209
68100	60-810 Band Pusher	33209
68101	60-810A Band Pusher Silicon Handle	33209
68110	60-811 Band Pusher Trihedral Handle	33209
68150	60-815 Bracket Placing Tweezers	33209
68160	60-816 Ligature Director	33209
68170	60-817 Ligating & Director (with Pin)	33209
68171	60-817N Ligating & Director (without Pin)	33209
68180	60-818 Ligature Director - Double End	33209
68190	60-819 Ligature Director - Single End	33209
68220	60-822 Lingual Tucker	33209
68230	60-823 Ligature Director	33209
68240	60-824 Bracket Tweezers	33209
68250	60-825 Bracket Setting Instrument	33209
68270	60-827 Ligature Director & Bracket Opener	33209
68300	60-830 Boon Bracket Positioning Gauge	33209
68410	60-841 Arch Turret	33209
68500	60-850 Lingual Arch Turret	33209
68900	60-890 Bracket Setting Tweezers	33209
69000	60-900 Tie-Back Plier	33209
69500	30-950 Replacement Hold-Ring (10/pk)	33209
69600	60-960 Replacement Metal Tip (5/pk)	33209
69700	60-970 Replacement Metal Tip	33209
69800	60-980 Replacement Metal Tip	33209
69830	60-983 Replacement Peek Tip (3/pk)	33209
69860	60-986 Replacement Aluminum Tip (3/pk)	33209
69861	TS-986 Replacement Aluminum Tip (3/pk)	33209
69871	60-9871 Replacement Metal Tip	33209
69872	60-9872 Replacement Silicone Tube	33209
70456	40-456 Tweed Loop Forming Plier O'Brien	33209
72005	CUTVLSB1 Vertical Loop & Step Bend Plier 1	33209
72006	CUTVLSB3 Vertical Loop & Step Bend Plier 3	33209
72007	CUTVLSB2 Vertical Loop & Step Bend Plier 2	33209
74314	Clasp Forming Plier Type III Inserted	33209
74822	SH Diamond Ligature Director	33209
Dental prosthesis remover		
18010	Crown Remover	35552
18015	Metal Crown Remover	35552
18025	Temporary Crown Remover T-Type I	35552
18026	Temporary Crown Remover T-Type II	35552
18027	Temporary Crown Remover T-Type III	35552
Dental wax carver		
40111	Hybrid Ceramics & Hard Resin Former #1	35794
40112	Hybrid Ceramics & Hard Resin Former #2	35794
40113	Hybrid Ceramics & Hard Resin Former #3	35794
41001	Evans Carver #1	35794

Product Code	Product Name	GMDN
Dental wax carver		
41002	Evans Carver #2	35794
41003	Evans Carver #3	35794
41005	Evans Carver #5A Silicone Handle	35794
41100	Evans Mini	35794
41101	New Wax Modeling Carver	35794
41150	Le Cron Carver	35794
Rubber dam punch		
03310	Rubber Dam Punch Forceps	35851
Rubber dam clamp forceps		
03320	Rubber Dam Clamp Forceps Brewer Type	35851
03321	Rubber Dam Clamp Forceps Stoke Type	35851
Dental spatula, reusable		
08501	Cement Spatula Double End #1	38530
08522	Cement Spatula Single End #22	38530
08524	Cement Spatula Single End #24	38530
08536	Cement Spatula Single End #36	38530
08600	Plaster Spatula	38530
08610	Alginate Spatula	38530
08611	Alginate Spatula With Opener	38530
08710	Speed Spatula	38530
42001	Wax Spatula Double End #1	38530
42002	Wax Spatula Double End #2	38530
42007	Wax Spatula Double End #7A	38530
42031	Wax Spatula Double End #31	38530
42080	Wax Spatula Double End Flat	38530

Version History

Version	Compiled by	Date	Description
1.0	Kenneth Shaw	4 August 2020	First issue under MDR.
1.1	Jun Matsuda	1 July 2021	Revised List