



MANUFACTURER'S EU DECLARATION OF CONFORMITY

General Description of device(s): The Medivance Instruments Ltd. AquaCare range of devices are Micro Air Abrasion and Polishing units used for short term orally invasive medical dentistry procedures carried out by dental health professionals.

Medivance Instruments Ltd. herewith declares that under our sole responsibility that the products:

BASIC-UDI: 506020958AquaCareZN

GMDN	Device name	Part No.	UDI-DI
45403	AquaCare MK5 Single Chamber Dental Air Abrasion Unit	I/MAC 8503F	5060209580005
45403	AquaCare MK5 Twin Chamber Dental Air Abrasion Unit	I/MAC 8502F	5060209580012
45403	AquaCare MK5 Twin Chamber Black Edition Dental Air Abrasion Unit	I/MAC 8508F	5060209580029
45407	29 µm Aluminium Oxide Dental Powder for intra oral use	I/PDR 8025F	5060209580135
45407	53 µm Aluminium Oxide Dental Powder for intra oral use	I/PDR 8024F	5060209580142

To which this declaration relates are **CE marked** in accordance to the requirements of the following outlined European Council Directives and International ISO standards. The Conformity Assessment route used was the **Medical Device Directive 93/42/EEC Annex II** (excluding section 4).

BS EN ISO 1639:2009	Dentistry - Medical Devices for dentistry Instrumentation
BS EN 13402:2001	Surgical and Dental Hand Instruments - Determination of Resistance against autoclaving, corrosion and thermal exposure
BS EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
PD ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
BS EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation & testing within a risk management process

Under specification of Medical Device Directive 93/42/EEC Rule 5 of Annex IX and Regulation (EU) 2017/745 Rule 5 of Annex VIII, the above declared devices are classified as Class IIa.

Under Article 120 (3a), point b of Regulation (EU) 2023/607 amendment to Regulation (EU) 2017/745, compliance is granted for MDD 93/42/EEC Certified devices under Legacy Devices until 31 December 2028.

Each unit is supplied with Installation Instructions and an Operating Instructions Manual, and is to be maintained and used by dental health professionals.

Identification: Each unit is individually Serial Numbered and Date Coded.

Please see the subsequent Appendix A, B and C for listing of all consumables, accessories and spare parts.

Directive 93/42/EEC (CE) approval - Ref Certificate GB19/964437 - Notified Body 1639 SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium. Tel: +32 (0)3 545-48-49

This declaration is further supported by the Quality Management System approval to ISO 13485:2016 issued by SGS:

BS EN ISO 13485:2016 - Ref Certificate GB00/51496 - SGS United Kingdom Ltd., Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK. Tel: +44(0) 151 350-6666

The following Authorised Representatives have been appointed by Medivance Instruments Ltd.:

- European Authorised Representative (E.A.R.): MEDNET EC-REP GmbH Borkstrasse 10 48163 Muenster Germany Local Reg No HRB 17791, SRN: DE-AR-000000002**

For and on behalf of Medivance Instruments Ltd. (SRN: GB-MF-000024293)

Brian Williams
Quality Assurance Manager

Form MDoC Issue 13

FOR AND ON BEHALF OF
MEDIVANCE INSTRUMENTS LTD

Date: 13/04/2023



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<u>Recommended Consumables *</u>	<u>Qty</u>	<u>Part No</u>	<u>UDI-DI</u>	<u>Class</u>
Sylc Bioactive Powder Cartridges (Green label)	Pack of 4	I/PDR 0034F *	5060209580173	I
Sodium Bicarbonate Fine Cartridges (White label)	Pack of 4	I/PDR 8014F *	-	N/A
Sodium Bicarbonate Soft Microfine Cartridges (Turquoise label)	Pack of 4	I/PDR 8015F *	-	N/A
29 µm Aluminium Oxide Cartridges (Blue label)	Pack of 4	I/PDR 8025F *	5060209580135	IIa
53 µm Aluminium Oxide Cartridges (Red label)	Pack of 4	I/PDR 8024F *	5060209580142	IIa
Feedlines and Tips (<i>Standard</i>)	Pack of 50	I/ASS 8007F *	5060209580203	IIa
Feedlines and Tips (<i>iTips</i>)	Pack of 50	I/ASS 8009F *	5060209580227	IIa
Feedlines and Tips (<i>Plus Tips</i>)	Pack of 50	I/ASS 8008F *	5060209580210	IIa
Handpiece Handles (Plastic)	Pack of 5	I/ASS 8024F *	-	N/A
Handpiece Stainless Steel 0.6mm (<i>Silver ring</i>)	Pack of 1	I/ASS 8191F *	5060209580234	IIa
Handpiece Black 0.6mm (<i>Silver ring</i>)	Pack of 1	I/ASS 8188F *	5060209580258	IIa
Handpiece Stainless Steel 0.8mm (<i>Gold ring</i>)	Pack of 1	I/ASS 8192F *	5060209580241	IIa
Handpiece Black 0.8mm (<i>Gold ring</i>)	Pack of 1	I/ASS 8189F *	5060209580265	IIa
AquaSol 500ml (Fluid)	Pack of 1	I/PAC 8200F *	5060209580180	I
AquaSol 500ml (Fluid) Multipack	Pack of 6	I/PAC 8206F *	5060209580197	I
Chalk Stick	Pack of 1	I/ASS 9316F	-	N/A
Glass Slides (for cutting practice)	Pack of 5	I/MIC 0010F	-	N/A

<u>Recommended Accessories</u>	<u>Qty</u>	<u>Part No</u>	<u>UDI-DI</u>	<u>Class</u>
Nozzle Wash Syringes	Pack of 2	I/ASS 8025F	-	N/A
Handpiece Tube Removal Tool	Pack of 1	I/ASS 8625F	-	N/A
Nozzle Cleaning Wires	Pack of 1	I/ASS 8073F	-	N/A
Quick Release twin tube feed Assembly	Pack of 1	I/ASS 8020F	-	N/A
Quick Release Black twin tube feed Assembly	Pack of 1	I/ASS 8021F	-	N/A

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<u>Recommended Accessories</u>	Qty	Part No	UDI-DI	Class
Foot Pedal Assembly (Original)	Pack of 1	I/ASS 8153F	5060209580357	I
Ergo Foot Pedal Assembly	Pack of 1	I/ASS 9700F	5060209580364	I
Ergo Foot Pedal Assembly (Black Edition)	Pack of 1	I/ASS 9699F	5060209580371	I
In Line Air Filter	Pack of 1	I/ASS 0320F	-	N/A
6mm Input Air Hose (Grey)	Pack of 1	I/ASS 8016F	-	N/A
Purge Bottle	Pack of 1	I/ASS 8215F	-	N/A
Powder Pot - Storage Container	Pack of 1	I/ASS 8193F	-	N/A
AquaCare Dry Air Unit	Pack of 1	I/MAC 8552F	5060209580036	I
AquaCare Dry Air Unit (Black Edition)	Pack of 1	I/MAC 8522F	5060209580043	I
AquaCare Stand (Twin)	Pack of 1	I/MAC 8513F	-	N/A
AquaCare Stand (Twin Black Edition)	Pack of 1	I/MAC 8514F	-	N/A
AquaCare Stand (Single)	Pack of 1	I/MAC 8516F	-	N/A
AquaCare Stand with Dry Air Unit (Twin)	Pack of 1	I/MAC 8553F	5060209580098	I
AquaCare Stand with Dry Air Unit (Twin Black Edition)	Pack of 1	I/MAC 8523F	5060209580104	I
AquaCare Stand with Dry Air Unit (Single)	Pack of 1	I/MAC 8554F	5060209580081	I
Dental Air Abrasion Cabinet	Pack of 1	I/MAC 6200F	-	N/A

We hereby certify that the above items can be supplied for the devices as listed on the Manufactures Declaration of Conformity for the following devices:

- AquaCare Single Air Abrasion Unit (part number: I/MAC 8503F, UDI-DI: 5060209580005)
- AquaCare Twin Air Abrasion Unit (part number: I/MAC 8502F, UDI-DI: 5060209580012)
- AquaCare Twin Air Abrasion Unit Black Edition (part number: I/MAC 8508F, UDI-DI: 5060209580029)

Signed for and on behalf of Medivance Instruments Ltd. (SRN: GB-MF-000024293)

Brian Williams
Quality Assurance Manager

FOR AND ON BEHALF OF
MEDIVANCE INSTRUMENTS LTD



Form MDOC - AA Iss. 15_03.2023

Dated: 09.03.2023



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<u>Spare Parts</u>	Qty	Part No	Class
Dosing Chamber Lid Assembly *	Pack of 1	I/ASS8003F	N/A
Dosing Chamber Lid Assembly (black edition)	Pack of 1	I/ASS8002F	N/A
Check Valve Assembly *	Pack of 2	I/ASS8004F	N/A
<i>Dosing Chamber Assembly (Pre- Feb 2019 Twin) *</i>	Pack of 1	I/ASS8005F	N/A
<i>Dosing Chamber Assembly (Pre- May 2020 Single) *</i>	Pack of 1	I/ASS8005F	N/A
Filter Assembly *	Pack of 1	I/ASS8012F	N/A
<i>Pilot Valve Assembly (Pre- May 2019 Twin) *</i>	Pack of 1	I/ASS8101F	N/A
<i>Pilot Valve Assembly (Pre- April 2019 Single) *</i>	Pack of 1	I/ASS8101F	N/A
Vibrator Assembly *	Pack of 1	I/ASS8104F	N/A
<i>Fluid Valve Assembly (Pre- May 2019 Twin) *</i>	Pack of 1	I/ASS8126F	N/A
<i>Fluid Valve Assembly (Pre- April 2019 Single) *</i>	Pack of 1	I/ASS8126F	N/A
Foot Pedal Air Router Assembly *	Pack of 1	I/ASS8152F	N/A
New Dosing Chamber Assembly (Post- Feb 2019 Twin)	Pack of 1	I/ASS9219F	N/A
New Dosing Chamber Assembly (Post- May 2020 Single)	Pack of 1	I/ASS9219F	N/A
New On /Off Switch /Pinch (Post- Feb 2019 Twin)	Pack of 1	I/ASS9301F	N/A
New On /Off Switch /Pinch (Post- May 2020 Single)	Pack of 1	I/ASS9301F	N/A
New On /Off Switch /Pinch (black edition)	Pack of 1	I/ASS9300F	N/A
New Manifold Block Assembly (Post- May 2019 Twin)	Pack of 1	I/ASS9302F	N/A
New Manifold Block Assembly (Post- May 2019 Single)	Pack of 1	I/ASS9302F	N/A
New Regulator "Power" (Post- Dec 2018 Twin)	Pack of 1	I/ASS9307F	N/A
New Regulator "Power" (Post- Jan 2019 Single)	Pack of 1	I/ASS9307F	N/A
New Water Pinch Valve Assembly (Post- Dec 2018 Twin)	Pack of 1	I/ASS9308F	N/A
New Water Pinch Valve Assembly (Post- Dec 2018 Single)	Pack of 1	I/ASS9308F	N/A
New Water Pinch Valve Assembly "Retrofit Kit" Twin	Pack of 1	I/ASS9321F	N/A
New Water Pinch Valve Assembly "Retrofit Kit" Twin (black)	Pack of 1	I/ASS9325F	N/A
New Water Pinch Valve Assembly "Retrofit Kit" Single	Pack of 1	I/ASS9322F	N/A
New Water Pinch Valve Assembly "Retrofit Kit" Single (black)	Pack of 1	I/ASS9326F	N/A
New Regulator "Vibrator" (Post- Dec 2018 Twin)	Pack of 1	I/ASS9310F	N/A
New Regulator "Vibrator" (Post- Jan 2019 Single)	Pack of 1	I/ASS9310F	N/A
New Two-Way Connector Assembly *	Pack of 1	I/ASS9320F	N/A



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Spare Parts	Qty	Part No	Class
2 Way Connector + Check Valve Tube	Pack of 1	I/ASS9323F	N/A
Dosing Chamber Lid Round Seal *	Pack of 1	I/FIT9936F	N/A
(Note - Star Seal Replacement)			
Twin Pot Cam	Pack of 1	I/FIT0059F	N/A
Twin Pot 4mm Cam "O-Ring"	Pack of 1	I/FIT0093F	N/A
Pressure Gauge 4mm LPCF Coupling Nut	Pack of 1	I/FIT0194F	N/A
Pressure Gauge 0-10 Bar *	Pack of 1	I/FIT8030F	N/A
Pressure Gauge 0-4 Bar *	Pack of 1	I/FIT8041F	N/A
Media Gauge *	Pack of 1	I/FIT8042F	N/A
Regulator "Power/Vibrator" (Pre- Jan 2019 Twin) *	Pack of 1	I/FIT8044F	N/A
Regulator "Power/Vibrator" (Pre- Feb 2019 Single) *	Pack of 1	I/FIT8044F	N/A
On /Off Switch (Pre- Feb 2019 Twin)	Pack of 1	I/FIT8057F	N/A
On Off Switch (Pre- May 2020 Single)	Pack of 1	I/FIT8057F	N/A
Filter Element White (Twin Pack) *	Pack of 2	I/FIT8186F	N/A
Foot Pedal - Lifting Arch *	Pack of 1	I/FIT8929F	N/A
Regulator Securing Nut *	Pack of 1	I/FIT9948F	N/A
Pilot Valve	Pack of 1	I/FIT9953F	N/A
Twin Pot Cam 4mm Circlip	Pack of 1	I/FIX0058F	N/A
PRV Pressure Release Valve *	Pack of 1	I/FIX2173F	N/A
Twin Pot Cam - Stop Block	Pack of 1	I/MDG0008F	N/A
AquaCare Gaiter (Universal)	Pack of 1	I/MDG0017F	N/A
AquaCare Gaiter (Universal) (black edition)	Pack of 1	I/MDG9807F	N/A
Twin Pot Cam Pinch Top	Pack of 1	I/MDG0068F	N/A
Twin Pot Cam Knob	Pack of 1	I/MDG0096F	N/A
Twin Pot Cam Knob (black edition)	Pack of 1	I/MDG9804F	N/A
Single Pot Water Valve Knob (Pre- Feb 2019 Device)	Pack of 1	I/MDG1019F	N/A
Regulator Control Knobs (Pre- Feb 2019)	Pack of 1	I/MDG1030F	N/A
Regulator Control Knob	Pack of 1	I/MDG1020F	N/A
Regulator Control Knob (black edition)	Pack of 1	I/MDG9802F	N/A
AquaCare On - Off Switch Cap (Universal)	Pack of 1	I/MDG1025F	N/A
AquaCare On - Off Switch Cap (Universal) (black edition)	Pack of 1	I/MDG9803F	N/A
Foot Pedal Lid Rubber *	Pack of 1	I/MDG8039F	N/A

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Spare Parts	Qty	Part No	Class
<i>Pinch Valve (Pre- May 2019 Device) *</i>	Pack of 2	I/MDG8056F	N/A
<i>Pinch Bracket (Pre- May 2019 Device)</i>	Pack of 1	I/MDG8080F	N/A
Dosing Chamber Lid Seal White *	Pack of 1	I/MDG8117F	N/A
New Slim Pinch (Post- May 2019)	Pack of 1	I/MDG9605F	N/A
New Pinch Bracket (Post- May 2019)	Pack of 1	I/MDG9603F	N/A
Pinch Valve Tubing (3m Length) *	Pack of 1	I/ROL8004F	N/A
Foot Pedal Tubing (4 Way & 2m length) *	Pack of 1	I/ROL8100F	N/A
Dosing Chamber Mount Springs *	Pack of 4	I/SPR0006F	N/A
3 Port Valve (Pre- Feb 2018)	Pack of 1	I/FIT0335F	N/A
Regulator & Air Filter Spanner	Pack of 1	I/FIT9947F	N/A
Mount Bracket - Pillar Sleeve	Pack of 1	I/MDG9621F	N/A
Air Router Seal (Black)	Pack of 1	I/MDG8038F	N/A
Anti-Pull-out Bracket	Pack of 1	I/MDG9617F	N/A
Empty Fluid Bottle assembly 500ml	Pack of 1	I/ASS8201F	N/A

*Please Note: Items shown in Italics are for earlier AquaCare device models as indicated, whilst those marked with * are compatible with AquaCut Quattro Junior and Quattro Air Abrasion Units.*

We hereby certify that the above items can be supplied for the devices as listed on the Manufactures Declaration of Conformity for the following devices:

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- AquaCare Twin Air Abrasion Unit (part number: I/MAC 8502F, UDI-DI: 5060209580012)
- AquaCare Twin Air Abrasion Unit Black Edition (part number: I/MAC 8508F, UDI-DI: 5060209580029)

Signed for and on behalf of Medivance Instruments Ltd. (SRN: GB-MF-000024293)

FOR AND ON BEHALF OF
MEDIVANCE INSTRUMENTS LTD

Brian Williams
Quality Assurance Manager



Date: 28.02.2023

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<u>Spare Parts for Stand</u>	<u>Qty</u>	<u>Part No</u>	<u>Class</u>
Support plate assembly	Pack of 1	White: I/ASS8527F Black: I/ASS8529F	N/A
Middle plate support	Pack of 1	I/MDG9623F	N/A
Stand base assembly	Pack of 1	White: I/ASS 8528F Black: I/ASS 8512F	N/A
Caster front wheels	Pack of 2	I/FIT0157F	N/A
Caster rear wheels (split)	Pack of 2	I/FIT0158F	N/A
Rear axle rod	Pack of 1	I/MDG9209F	N/A
Air filter assembly	Pack of 1	I/ASS0320F	N/A
Air filter bracket	Pack of 1	White: I/FIT9942F Black: I/FIT9944F	N/A
<u>Spare Parts for DryAir</u>			
Dry box cover and frame set	Pack of 1	White: I/ASS8558F Black: I/ASS8559F	N/A
Dry box dosing chamber assembly	Pack of 2	I/ASS8554F	N/A
Replacement activated alumina desiccant (for 2 chambers)	Pack of 1	I/FIX9700F	N/A
Polyurethane tube clear 4mm outer diameter 3m	Pack of 1	I/ROL8004F	N/A
Non return valve	Pack of 2	I/FIT8172F	N/A
Dry box cam partial assembly	Pack of 1	White: I/ASS8560F Black: I/ASS8561F	N/A

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- AquaCare Twin Air Abrasion Unit Black Edition (part number: I/MAC 8508F, UDI-DI: 5060209580029)

Signed for and on behalf of Medivance Instruments Ltd. (SRN: GB-MF-000024293)

Brian Williams

Quality Assurance Manager

FOR AND ON BEHALF OF
MEDIVANCE INSTRUMENTS LTD

Date: 10.02.2023



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