

PART I: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR HEALTHCARE PROFESSIONALS

Document revision: V2

Date issued: 26/08/2026

Manufacturer's reference number for the SSCP: 1037-ELSE-033

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals and other intended users requiring a technical summary of the safety and clinical performance of the EquilS Automated Insulin Delivery System.

1. Device identification and general information

Table 1 Device information

1.1 Device trade name(s)	EquilS Automated Insulin Delivery System
Abbreviated name	EquilS AID System
1.2 Manufacturer's name and address	Manufacturer: MicroTech Medical (Hangzhou) Co., Ltd. Address: No.108, Liuze Street, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang Province, China.
1.3 Manufacturer's Single Registration Number	CN-MF-000001157
1.4 Basic UDI-DI	Automated Insulin Delivery System: 69585903Z120402AIDSCX
1.5 Medical device nomenclature description / text	EMDN code(s): AID System: Z12040211 Insulin Patch Pump / PDA / EquilS APP: Z12040216; compatible CGMS: Z120401;
1.6 Class of device	Class III
1.7 Year when the first CE certificate was issued covering the device	At the time of this SSCP preparation, the device is undergoing initial MDR conformity assessment; no CE certificate has yet been issued for the EquilS Automated Insulin Delivery System.
1.8 Authorized representative	EU Authorized Representative: CMC Medical Devices & Drugs S.L. Address: C/ Horacio Lengo no18, 29006 Málaga, Spain. Single Registration Number: ES-AR-000000293.
1.9 Notified Body	Notified Body: TÜV Rheinland LGA Products GmbH. Notified Body identification number: 0197. Address/contact: Tillystrasse 2, 90431 Nurnberg, Germany

2. Intended use of the device

2.1 Intended purpose(s)

The EquilS Automated Insulin Delivery System is intended for continuous subcutaneous delivery of insulin at set and variable rates for the management of type 1 diabetes mellitus in persons 2 years of age and older who require insulin infusion. When

used with a compatible continuous glucose monitoring system (CGMS), the system can automatically adjust basal insulin delivery based on sensor glucose values. The system can also operate in Manual Mode for insulin delivery.

2.2 Indication(s) and target population(s)

Indications: The EquilS Automated Insulin Delivery System is indicated for use in persons 2 years of age and older with type 1 diabetes mellitus who require insulin therapy.

Target population(s): Persons 2 years of age and older with type 1 diabetes mellitus who require insulin therapy and who can use the device safely themselves or with support from a caregiver, guardian, or healthcare professional.

2.3 Contraindications

The EquilS Automated Insulin Delivery System is not recommended for the following groups of individuals:

- 1) Individuals with intellectual disabilities who cannot comprehend or master the relevant knowledge of this system.
- 2) Pediatric patients whose parents, guardians or caregivers are unable to learn how to operate the system.
- 3) Individuals allergic to insulin.
- 4) Individuals with psychiatric disorders that may interfere with the safe use of the system.
- 5) Individuals who are unable to monitor blood glucose levels as recommended by their healthcare provider.
- 6) Individuals who are unable to maintain contact with their healthcare provider.
- 7) Individuals taking acetaminophen at doses higher than the maximum recommended dose (for example, more than 1 gram every 6 hours in adults), as it may cause CGMS readings to appear falsely elevated.
- 8) Individuals who do not have adequate hearing and/or vision to recognize all functions of the EquilS System, including alerts, alarms, and reminders.
- 9) Pregnant women, as the EquilS System has not been evaluated in this population.
- 10) Individuals undergoing dialysis.

3. Device description

3.1 Description of the device

The EquilS Automated Insulin Delivery System is a system-level automated insulin delivery device consisting of an Insulin Patch Pump, a Portable Diabetes Assistant (PDA), the Insulin Patch Pump Control Mobile Application (EquilS APP), and compatible CGMS sensors. The PDA and the APP can each function as the user interface and controller of the system. Users may select either the PDA or the APP as the primary control interface according to the Instructions for Use and applicable software configuration.

The Insulin Patch Pump delivers insulin subcutaneously by controlling the movement of an internal motor-driven push rod, which advances the reservoir plunger to deliver insulin according to programmed delivery settings. The PDA/APP wirelessly sends settings or commands to the pump and receives pump status and alarm information for display to the user.

In Automated Mode, the pump receives sensor glucose information from the compatible CGMS and dynamically adjusts basal insulin delivery according to the hybrid closed-loop algorithm. In Manual Mode, the system functions as an insulin patch pump delivering user-programmed basal insulin and user-initiated bolus insulin.

The principal system components and configurations are summarized below.

Table 2 System components

Component	Model / configuration	Function / description	Service life	Basic UDI-DI
Insulin Patch Pump	MTM-Z1	Reusable pump for continuous subcutaneous insulin delivery, manual bolus delivery, communication with PDA/APP and compatible CGMS, and automated basal adjustment in Auto Mode.	4 years	N/A. This product is not placed on the market as a standalone device, but is instead placed on the market as part of a system together with either a PDA or an APP as the receiver. Therefore, it does not have an independent Basic UDI-DI.
Portable Diabetes Assistant	MTM-Z2	Reusable controller and user interface for therapy settings, pump/CGMS pairing, alarms, data display, and operation of insulin delivery functions.	4 years	69585903Z120402CLPDAZM
Insulin Patch Pump Control Mobile Application	MTM-APP-A (Android); MTM-APP-I (iOS)	Software controller and user interface for compatible mobile platforms according to the final IFU and software configuration.	Reusable software	APP (MTM-APP-A): 69585903Z120402CLAPPAND75 APP(MTM-APP-I): 69585903Z120402CLAPPIOS9E
Compatible CGMS Sensor	GX-01S, GX-02S, GX-01F, GX-02F	Provides sensor glucose values used for display and automated basal adjustment. Standalone CGMS performance is addressed in the relevant CGMS technical and clinical documentation.	15 days for GX-01S/GX-01F; 10 days for GX-02S/GX-02F	CGMS Sensor(GX-01S, GX-02S):69585903Z1204011502GXSDM CGMS Sensor(GX-01F, GX-02F):69585903Z120401GXE4Y

The system is used together with MicroTech-specified disposables for insulin storage and subcutaneous infusion. These disposables are clinically relevant to insulin delivery continuity, infusion-site safety, and overall system use, but their component-specific clinical evaluation is addressed in separate disposables documentation.

Table 3 Information of Disposables

Disposables used together with the system	Models	Clinical relevance
Insulin Infusion Pump Reservoir	MTM-3A; MTM-10A	Stores compatible U-100 insulin and interfaces with the Insulin Patch Pump for insulin delivery.
Insulin Infusion Set	HRN-S1-60; HRN-S1-90; HRN-S2-45; HRN-S2-60; HRN-S2-70; HRN-S2-80; HRN-S2-90 with MTM-4A base plate	Provides the subcutaneous infusion pathway. Infusion-site events, interruption of insulin delivery, and use-related handling are considered in system-level clinical risk evaluation.

3.2 A reference to previous generation(s) or variants, if such exist, and a description of the differences

MicroTech Medical has previously marketed standalone insulin pump systems intended for continuous subcutaneous insulin infusion. These predecessor pump products provide manually programmed insulin delivery but do not incorporate the integrated CGMS-driven automated basal insulin adjustment function of the EquiS Automated Insulin Delivery System.

The EquiS Automated Insulin Delivery System integrates a compatible continuous glucose monitoring system, automated basal insulin adjustment through a hybrid closed-loop control algorithm, and system-level communication among the insulin pump, PDA or mobile application controller, and CGMS. These functions distinguish the EquiS AID System from the manufacturer's earlier standalone/open-loop pump systems.

No formal MDR equivalence claim to a predecessor or comparator device is used to support the clinical performance claims of the EquiS Automated Insulin Delivery System.

3.3 Description of any accessories intended to be used in combination with the device

Table 4 Description of Accessories

Accessory	Model	Description
Pump Charging Dock	1037-SMTL-006	Reusable accessory used for charging the Insulin Patch Pump together with the charging cable.
Charging Cable	1037-RMTL-605	Reusable accessory used for charging the PDA directly and charging the Insulin Patch Pump when connected to the charging dock.
Medical Power Supply	1001-RMTL-541	Reusable accessory used to supply power for charging according to the IFU.
Cannula Inserter	1037-SMTL-216	Reusable accessory used to support insertion of compatible separable infusion sets, where applicable.

3.4 Description of any other devices and products intended to be used in combination with the device

The EquilS Automated Insulin Delivery System is intended to be used with compatible MicroTech CGMS models specified in the Instructions for Use and with MicroTech-specified insulin delivery disposables. The device shall only be used with compatible U-100 insulin products specified in the Instructions for Use. Third-party consumables or non-compatible products may result in inaccurate insulin delivery, device malfunction, or unacceptable clinical risk.

4. Risks and warnings

4.1 Residual risks and undesirable effects

The risks associated with the EquilS Automated Insulin Delivery System have been evaluated through the risk management process and clinical evaluation. Clinically relevant residual risks and undesirable effects include hypoglycaemia, severe hypoglycaemia, hyperglycaemia, severe hyperglycaemia, ketosis or diabetic ketoacidosis (DKA), insulin under-delivery or over-delivery, interruption of insulin delivery, infusion-site or skin reactions, device-related adverse events, device deficiencies, communication interruption, alarm- or response-related issues, and foreseeable use-related events.

Quantitative safety data are available from the manufacturer-sponsored prospective pre-market clinical investigations CI04 and CI03. The observed frequencies are shown below. The safety data were collected over the respective clinical investigation periods, with total subject participation of approximately 5 months in CI04 and approximately 4.5 months in CI03. These observed frequencies should not be interpreted as lifetime incidence rates.

Table 5 Quantitative safety data

Safety outcome	Adult CI04, N=101	Pediatric CI03, N=129
Subjects with any adverse event	31/101 (30.7%)	86/129 (66.7%)
Subjects with serious adverse events	0/101 (0%)	6/129 (4.7%)
Subjects with device-related adverse events	5/101 (5.0%)	16/129 (12.4%)
Severe hypoglycaemia	0/101 (0%)	11/129 (8.5%)
Severe hyperglycaemia	1/101 (1.0%)	11/129 (8.5%)
Diabetic ketoacidosis	0/101 (0%)	2/129 (1.6%)
Device-related serious adverse events	0/101 (0%)	2/129 (1.6%)

In CI04, no serious adverse event, severe hypoglycaemia event, or DKA event was reported. One severe hyperglycaemia event occurred and was assessed as not device-related. Device-related adverse events occurred in 5 subjects and were limited to skin-related reactions.

In CI03, 2 subjects experienced device-related serious adverse events; both events were DKA and both subjects recovered. Severe hypoglycaemia and severe hyperglycaemia were also observed in the pediatric investigation. Device-related adverse events included skin reactions and glucose-related events. One subject discontinued the investigation because of skin allergy.

The observed events are consistent with the known residual-risk domains of insulin pump therapy and automated insulin delivery. The clinical acceptability of these risks has been assessed in the Clinical Evaluation Report together with event

seriousness, device relationship, outcome, risk controls, Instructions for Use, user and caregiver training, and the demonstrated clinical benefits.

Other residual risks, including insulin under-delivery or over-delivery, therapy interruption, incorrect therapy settings, inaccurate or delayed CGMS values, communication interruption, unexpected exit from Auto Mode, alarm-response issues, and software- or controller-related interruption, are controlled through device design, verification and validation, alarms and notifications, usability engineering, user training, Instructions for Use, and risk-management measures. Their detailed risk evaluation is maintained in the applicable risk-management documentation.

4.2 Warnings and precautions

Users, including patients and caregivers/guardians, must receive professional training before using the device. A healthcare professional should establish and adjust the insulin pump therapy plan. Initiating therapy or modifying pump, PDA, or APP settings without appropriate training and supervision may result in incorrect insulin delivery and may lead to hypoglycaemia or hyperglycaemia.

Users must understand diabetes management, including glucose monitoring, recognition and management of hypoglycaemia and hyperglycaemia, meal-related bolus administration, and the need for backup insulin delivery if pump therapy is interrupted. Users should maintain contact with their healthcare professional and adjust therapy settings only as medically advised.

Only compatible rapid-acting U-100 insulin products specified in the Instructions for Use may be used. The pump must not be filled with any other liquid, expired insulin, cloudy insulin, or insulin suspected to be compromised. Users must not administer insulin by another route while the pump is actively delivering insulin unless instructed by their healthcare professional, because insulin stacking may result in hypoglycaemia.

Only MicroTech Medical disposables specified for use with the system may be used. Sterile disposables shall not be used if packaging is damaged, opened unintentionally, or expired. The reservoir and infusion set are single-use components and shall be replaced according to the Instructions for Use. Used components containing needles shall be disposed of in accordance with local laws and regulations.

Infusion sites shall be prepared and rotated according to the Instructions for Use. The device shall not be applied to damaged, irritated, scarred, indurated, or otherwise compromised skin. Skin irritation or allergic reactions may occur and should be managed according to clinical judgement and the Instructions for Use.

In Auto Mode, manual insulin injection or infusion should not be performed unless medically necessary and managed according to the Instructions for Use, because active insulin estimation may be affected and excessive insulin delivery may occur. Meal bolus delivery remains required because CGMS measurements may lag during meals.

All components of the system, including the Insulin Patch Pump and sensor, shall be removed before MRI, CT scan, or diathermy treatment, and the controller shall be kept outside the procedure room. Users shall also follow the precautions relating to electromagnetic interference, wireless communication range, device damage, charging, temperature, water exposure, and airport/security procedures described in the Instructions for Use.

Individuals with coagulation disorders or those receiving anticoagulant therapy should consult a healthcare professional before use and monitor the CGM sensor and infusion-set insertion sites for signs of persistent or significant bleeding.

4.3 Other relevant aspects of safety, including a summary of any field safety action if applicable

Based on the vigilance/FSCA review available at the time of preparation, no FSCA or FSN has been identified for the EquiS Automated Insulin Delivery System.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

The clinical evaluation of the EquiS Automated Insulin Delivery System does not rely on a formal equivalence demonstration to another device for direct claim support. No equivalent device is claimed for the purpose of demonstrating conformity of the EquiS AID system. Evidence from benchmark or similar AID technologies is used only for state-of-the-art context, accepted endpoint interpretation, known risk identification, benchmark expectations, and benefit-risk interpretation.

5.2 Summary of clinical data from conducted investigations of the device before CE-marking

The pre-market clinical evidence for the EquiS Automated Insulin Delivery System includes two prospective, multicentre clinical investigations conducted in subjects with type 1 diabetes mellitus: CI04 in adults aged 18 years and older and CI03 in pediatric subjects aged 2–17 years. Both investigations evaluated within-subject changes in glycaemic outcomes between Manual Mode and Auto Mode and collected safety data throughout device use.

5.2.1 Adult pivotal clinical investigation – CI04

CI04 was a single-arm, prospective, multicentre clinical investigation conducted at nine clinical centres in China. A total of 109 subjects were screened, 101 were enrolled, and 99 completed the investigation. The Full Analysis Set (FAS) and Safety Set (SS) included 101 subjects, and the Per-Protocol Set (PPS) included 99 subjects.

The investigation included a screening period of 0–7 days, an approximately 2-week run-in period in Manual Mode, an approximately 4-week Manual Mode treatment period, an approximately 12-week Auto Mode treatment period, and an approximately 1-week safety follow-up.

The primary efficacy endpoint was the mean change in Time in Range (TIR), defined as sensor glucose 3.9–10.0 mmol/L, between Auto Mode and Manual Mode. In the FAS, mean TIR increased from 63.721% in Manual Mode to 74.522% in Auto Mode, corresponding to a mean increase of 10.802 percentage points (95% CI: 9.09 to 12.51; $p < 0.0001$). PPS results were consistent, with a mean increase of 10.751 percentage points (95% CI: 9.02 to 12.48; $p < 0.0001$).

In the FAS, Time Below Range (TBR) decreased by 1.503 percentage points for sensor glucose < 3.9 mmol/L, 0.745 percentage points for < 3.3 mmol/L, and 0.500 percentage points for < 3.0 mmol/L; all differences were statistically significant ($p < 0.0001$). Time Above Range (TAR) decreased by 9.298 percentage points for sensor glucose > 10.0 mmol/L, 4.013 percentage points for > 13.9 mmol/L, and 0.644 percentage points for > 19.4 mmol/L; all differences were statistically significant ($p < 0.0001$). HbA1c decreased from 7.09% before Auto Mode to 6.83% after Auto Mode, with a mean change of -0.25 percentage points ($p < 0.0001$).

In the Safety Set, 31/101 subjects (30.7%) experienced at least one adverse event. Device-related adverse events occurred in 5/101 subjects (5.0%), comprising seven events. No serious adverse event, device-related serious adverse event, severe hypoglycaemia event, or diabetic ketoacidosis event was reported. One severe hyperglycaemia event occurred and was assessed as not device-related. No adverse event led to discontinuation of device use.

5.2.2 Pediatric pivotal clinical investigation – CI03

CI03 was a single-arm, prospective, multicentre clinical investigation conducted at ten pediatric clinical centres in China. A total of 141 subjects were screened and 130 were enrolled, including 24 subjects aged 2–6 years and 106 subjects aged 7–17 years. Overall, 121 subjects completed the investigation. The FAS and SS included 129 subjects, and the PPS included 120 subjects.

The investigation included a screening period of 0–7 days, an approximately 2-week run-in period in Manual Mode, an approximately 4-week Manual Mode treatment period, an approximately 12-week Auto Mode treatment period, and an approximately 1-week safety follow-up.

The primary efficacy endpoint was the mean change in TIR, defined as sensor glucose 3.9–10.0 mmol/L, between Auto Mode and Manual Mode. In the FAS, TIR increased by 8.517 percentage points in subjects aged 2–6 years, 7.567 percentage points in subjects aged 7–17 years, and 7.716 percentage points overall. All comparisons were statistically significant ($p < 0.0001$). PPS results were consistent, with increases of 8.403, 7.567, and 7.692 percentage points, respectively.

In the FAS, TBR decreased by 0.770 percentage points for sensor glucose < 3.9 mmol/L, 0.193 percentage points for < 3.0 mmol/L, and 0.046 percentage points for < 3.0 mmol/L. The reduction for < 3.9 mmol/L was statistically significant. TAR decreased by 6.946 percentage points for sensor glucose > 10.0 mmol/L, 2.915 percentage points for > 13.9 mmol/L, and 0.374 percentage points for > 19.4 mmol/L; all differences were statistically significant ($p < 0.05$). Mean glucose, glucose variability and HbA1c also decreased in the FAS.

In the Safety Set, 86/129 subjects (66.7%) experienced at least one adverse event. Serious adverse events occurred in 6/129 subjects (4.7%). Device-related adverse events occurred in 16/129 subjects (12.4%), comprising 17 events. Device-related serious adverse events occurred in 2/129 subjects (1.6%); both were diabetic ketoacidosis events. Severe hypoglycaemia occurred in 11/129 subjects (8.5%), severe hyperglycaemia in 11/129 subjects (8.5%), and diabetic ketoacidosis in 2/129 subjects (1.6%). All device-related adverse events recovered according to the clinical investigation report. One subject discontinued the investigation due to a safety reason, namely skin allergy.

5.3 Summary of clinical data from other sources, if applicable

At the time of this initial MDR conformity assessment, no additional published clinical data specific to the EquiS Automated Insulin Delivery System are available beyond the manufacturer-sponsored pre-market clinical investigations described in Section 5.2. No completed PMCF clinical investigation or external device registry specific to the EquiS AID System is available at this stage.

State-of-the-art literature, clinical guidelines and consensus documents, benchmark AID clinical evidence, population-applicability evidence, vigilance information, risk-management outputs, software and algorithm verification, usability engineering, and other technical evidence were considered in the overall clinical evaluation as supportive or contextual evidence. These sources are not presented as additional device-specific clinical data.

5.4 Overall summary of clinical performance and safety

Based on the totality of available clinical evidence, the EquiS Automated Insulin Delivery System achieves its intended clinical performance when used in accordance with the Instructions for Use, individualized therapy settings, and professional training. The evaluated clinical data support improvement in Time in Range and reductions in Time Above Range and Time Below Range in both adult and pediatric T1D populations. HbA1c reduction was demonstrated in the adult FAS/PPS and in the pediatric FAS, while the pediatric PPS HbA1c reduction was not statistically significant and is therefore interpreted conservatively.

The clinical safety profile is acceptable for the intended purpose and target population when interpreted together with the risk management file, IFU warnings and precautions, training requirements, and current state of the art. The principal clinically relevant risks are known risks associated with insulin pump therapy, CGMS-supported AID therapy, software-controlled insulin delivery, pediatric/caregiver-supported use, and user-managed diabetes treatment. These risks are addressed through design controls, algorithm and software verification, system verification and validation, usability engineering, alarms and alerts, cybersecurity and data-continuity controls, risk management, professional training, backup therapy instructions, IFU warnings and precautions, and PMCF activities.

The overall benefit-risk profile is acceptable when the device is used by the intended users in the intended patient population and intended use environments. Residual risks and undesirable effects are considered acceptable when weighed against the clinically demonstrated glycaemic benefits and the risks associated with alternative diabetes management options, as documented in the clinical evaluation.

5.5 Ongoing or planned post-market clinical follow-up

Post-market clinical follow-up is planned to confirm the long-term clinical safety and clinical performance of the EquilS Automated Insulin Delivery System under routine use conditions and to identify any emerging clinically relevant risks or changes in the benefit-risk profile.

The primary specific PMCF activity is a planned multicentre, randomized, active-controlled, parallel-group clinical study in France comparing the EquilS Automated Insulin Delivery System with Omnipod 5 in adults with type 1 diabetes mellitus. The study includes a comparative study period followed by extended follow-up for long-term safety and performance through Week 52.

The PMCF programme also includes periodic review of relevant scientific literature and state-of-the-art information, vigilance information, complaints, device deficiencies, clinically relevant user feedback, and emerging safety or performance signals.

PMCF findings will be evaluated within the clinical evaluation lifecycle and will be used, where applicable, to update the Clinical Evaluation Report, risk-management documentation, SSCP, Instructions for Use, and other relevant technical documentation.

Refer to Post-Market Clinical Follow-up Plan 1037-TP-224, Version 2.

6. Possible diagnostics or therapeutic alternatives

Management of type 1 diabetes mellitus requires continuous insulin replacement together with glucose monitoring, education, and individualized adjustment of therapy. Available therapeutic approaches include multiple daily insulin injections, conventional continuous subcutaneous insulin infusion, sensor-augmented pump therapy, insulin-suspend technologies, and automated insulin delivery systems.

Multiple daily injections (MDI) provide insulin therapy without continuous pump attachment but require repeated injections and manual insulin-dose decisions.

Conventional continuous subcutaneous insulin infusion (CSII) provides programmable basal and bolus insulin delivery and may improve flexibility compared with injections, but insulin delivery is not automatically adjusted in response to sensor glucose values.

Sensor-augmented pump therapy and insulin-suspend systems combine insulin pump therapy with continuous glucose monitoring and may provide additional protection against hypoglycaemia, but provide less automated insulin adjustment than automated insulin delivery systems.

Automated insulin delivery systems combine insulin pump therapy, continuous glucose monitoring, and algorithm-controlled insulin adjustment. Their clinical performance, safety profile, compatible devices, usability characteristics, training requirements, and degree of automation vary between systems.

Current diabetes guidelines and consensus recommendations recognize automated insulin delivery as an established treatment option for appropriate persons with type 1 diabetes who can safely use the technology. Selection between available therapeutic options should be individualized according to age, glycaemic status, risk of hypoglycaemia, previous treatment, ability of the user or caregiver to operate the system safely, treatment goals, clinical circumstances, access, and patient preference.

The clinical evaluation of the EquilS Automated Insulin Delivery System considers these alternatives and the current state of the art when evaluating its clinical performance, safety and benefit-risk profile.

7. Suggested profile and training for users

The intended users of the EquilS Automated Insulin Delivery System are persons with type 1 diabetes mellitus who are able to understand and operate the system, caregivers or guardians of pediatric or dependent users, and trained healthcare professionals. Patients and caregivers must be able to recognize, understand, and respond appropriately to system information, alerts, alarms, reminders, and therapy-related safety instructions.

Patients and caregivers/guardians shall receive appropriate training from a healthcare professional before independent use of the system. Training should cover the functions relevant to the individual user, including system setup; pump, controller and compatible CGMS pairing; reservoir filling and infusion-set handling; infusion-site selection and rotation; basal and bolus delivery; bolus calculator use; Auto Mode operation; recognition and response to alerts and alarms; management of hypoglycaemia and hyperglycaemia; emergency preparedness; backup insulin therapy in the event of therapy interruption; charging and routine device care; and replacement and disposal of applicable single-use components.

For pediatric or dependent users, training shall include the caregiver or guardian responsible for operating or supervising the system. The level of independent operation should be appropriate to the user's age, capability and clinical circumstances.

Healthcare professionals responsible for initiation, therapy-setting adjustment or clinical follow-up should have appropriate knowledge and experience in type 1 diabetes management, insulin therapy, insulin pump therapy, continuous glucose monitoring and automated insulin delivery. They should also be familiar with the EquilS system functions relevant to clinical use, including individualized therapy settings, Auto Mode operation, interpretation of glucose information, alarms, troubleshooting, and management of clinically relevant adverse or use-related events.

Users should follow the Instructions for Use and the individualized instructions provided by their healthcare professional throughout use of the system.

8. Reference to any harmonized standards and common specifications applied

Table 6 Reference of applicable standards and applied specifications

Category	Identification Number	Name
Quality system	EN ISO 13485:2016 + AC:2018 + A11:2021 (ISO 13485:2016)	Quality Management Systems- Medical Devices – Requirements for regulatory purposes
	Regulation 2017/745	MDR
Risk management	EN ISO 14971:2019+A11:2021 (ISO 14971:2019)	Medical devices-Application of risk management to medical devices
	CEN ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
Labeling and information provided by the manufacturer	EN ISO 15223-1:2021+A1:2025 (ISO 15223-1:2021+A1:2025)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	EN ISO 20417:2026 (ISO 20417:2026)	Information supplied by the manufacturer of medical devices
Usability	EN 62366-1:2015+A1:2020 (IEC 62366-1:2015+AMD1:2020 CSV)	Medical devices - Application of usability engineering to medical devices

Software	EN 62304:2006+A1:2015 (IEC 62304:2006+A1:2015)	Medical device software - Software life cycle processes
Cybersecurity	IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security —Activities in the product life cycle
	EN ISO/IEC 27001:2023	Information security, cybersecurity and privacy protection—Information security management systems - Requirements
	ISO/IEEE 11073-40101:2022	Health informatics - Device interoperability Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment
	ISO/IEEE 11073-40102:2022	Health informatics - Device interoperability Part 40102: Foundational - Cybersecurity - Capabilities for mitigation
	EN IEC 80001-1:2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software
	MDCG 2019-16 Rev.1	Guidance on Cybersecurity for medical devices
Electrical safety	EN 60601-1:2006+A1:2013+A12:2014+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-6:2010+A1:2015+A2:2021 (IEC 60601-1-6:2010+AMD1:2013+AMD2:2020)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	EN 60601-1-8:2007+A2:2021 (IEC 60601-1-8:2006+AMD2:2020)	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
	EN 60601-1-10:2008/A2:2021 (IEC 60601-1-10:2007/A2:2020)	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
	EN 60601-1-11:2015+A1:2021	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
	EN 60601-2-24:2015 (IEC 60601-2-24:2012)	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EMC	EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
	IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
Radio equipment	Directive 2014/53/EU	Radio Equipment Directive (RED)
Stability	ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
	EN IEC 62506 2023 (IEC 62506: 2023)	Methods for product accelerated testing
	EN ISO 9227:2022 (ISO 9227-2022)	Corrosion tests in artificial atmospheres — Salt spray tests
Performance	EN 60529:1992+A2:2013	Degrees of protection provided by enclosures (IP Code)
	Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)

	Regulation (EC) No 1907/2006	REACH
	DIRECTIVE 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)
	Regulation (EU) 2023/1542	Batteries and waste batteries
Clinical evaluation	MEDDEV 2.7/1 Rev. 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
	MDCG 2020-5	Clinical Evaluation - Equivalence guide for manufacturers and notified bodies
	ISO 14155:2026	Clinical investigation of medical device for human subjects- Good clinical practice
	MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies
Post market	CEN ISO/TR 20416:2020	Post-market surveillance for manufacturers
	MDCG 2020-7	PMCF Plan Template
	MDCG 2020-8	PMCF Evaluation Report Template

9. Revision history

Revision	Changed by	Summary of Changes	Date of Change
V1	Zhaoxiong Chen	Initial Issue	29/06/2026
V2	Zhaoxiong Chen	Updated following first MDR technical documentation assessment	26/08/2026

PART II: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR PATIENTS

Document revision: V2

Date issued: 26/08/2026

This part gives patients and caregivers the main safety and performance information about the EquilS system. It does not replace the User Manual. Read the User Manual before use. Follow the advice of your healthcare professional.

1. Device identification and general information

Table 1 Device Identification and general information

1.1 Device trade name(s)	EquilS Automated Insulin Delivery System
Abbreviated name	EquilS AID System
1.2 Manufacturer's name and address	MicroTech Medical (Hangzhou) Co., Ltd. No.108, Liuze Street, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang Province, China.
1.3 Basic UDI-DI	Automated Insulin Delivery System: 69585903Z120402AIDSCX

2. Intended use of the device

2.1 Intended purpose(s)

The EquilS system gives insulin under the skin throughout the day for people with type 1 diabetes. In Manual Mode, it delivers insulin using settings chosen for the user. With a compatible CGMS, Auto Mode can change basal insulin based on sensor glucose readings. CGMS means continuous glucose monitoring system.

2.2 Indication(s) and target population(s)

The EquilS system is intended for people aged 2 years and older with type 1 diabetes who need insulin therapy. Children and people who cannot use the system independently may need help from a trained parent, guardian, or caregiver.

2.3 Contraindications

The EquilS Automated Insulin Delivery System system is not recommended for the following groups of individuals:

- 1) Individuals with intellectual disabilities who cannot comprehend or master the relevant knowledge of this system.
- 2) Pediatric patients whose parents, guardians or caregivers are unable to learn how to operate the system.
- 3) Individuals allergic to insulin.
- 4) Individuals with psychiatric disorders that may interfere with the safe use of the system.
- 5) Individuals who are unable to monitor blood glucose levels as recommended by their healthcare provider.
- 6) Individuals who are unable to maintain contact with their healthcare provider.
- 7) Individuals taking acetaminophen at doses higher than the maximum recommended dose (for example, more than 1 gram every 6 hours in adults), as it may cause CGMs readings to appear falsely elevated.

8) Individuals who do not have adequate hearing and/or vision to recognize all functions of the EquilS System, including alerts, alarms, and reminders.

9) Pregnant women, as the EquilS System has not been evaluated in this population.

10) Individuals undergoing dialysis.

3. Device description

The EquilS system has a patch insulin pump, a controller, a mobile app, and compatible CGMS sensors. The pump is worn on the body. It gives insulin through an infusion set under the skin. The PDA or mobile app controls the system and shows glucose readings, alarms, and reminders.

In Auto Mode, the system uses CGMS glucose readings to change basal insulin automatically. You still need to give meal boluses when required, respond to alarms, check glucose as advised, and use your backup insulin plan if pump therapy stops.

The system uses insulin reservoirs and infusion sets specified by MicroTech Medical. These parts are for single use. Replace them as described in the User Manual. Other accessories include the pump charging dock, charging cable, power supply, and cannula inserter, where applicable.

4. Risks and warnings

4.1 How potential risks have been controlled or managed

The manufacturer uses several ways to reduce risk. These include testing the device and software, alarms and alerts, user training, risk management, and instructions for safe use. If the wireless link between the pump and controller is lost, the pump can continue key insulin delivery using its current settings. Follow the User Manual and your backup treatment plan.

4.2 Remaining risks and undesirable effects

Some risks remain with the EquilS system, as with other insulin pumps and AID systems. These include very low glucose, very high glucose, diabetic ketoacidosis (DKA), interrupted insulin delivery, and skin reactions.

The adult study lasted about 5 months. The pediatric study lasted about 4.5 months. The numbers below show events observed during these study periods. They do not show the lifetime chance of an event.

Adult clinical study

Among 101 adults:

- Severe low glucose: 0 of 101 participants (0%).
- Severe high glucose: 1 of 101 participants (1.0%).
- DKA: 0 of 101 participants (0%).
- Device-related adverse events: 5 of 101 participants (5.0%).
- Serious adverse events: 0 of 101 participants (0%).

Pediatric clinical study

Among 129 children and adolescents:

- Severe low glucose: 11 of 129 participants (8.5%).

- Severe high glucose: 11 of 129 participants (8.5%).
- DKA: 2 of 129 participants (1.6%).
- Device-related adverse events: 16 of 129 participants (12.4%).
- Serious adverse events: 6 of 129 participants (4.7%).
- Serious device-related adverse events: 2 of 129 participants (1.6%). Both were DKA events, and both participants recovered.

Skin reactions can occur where the device or disposable parts touch the skin. They may include redness, itching, irritation, or allergy.

These percentages are from the clinical studies. They do not predict how often the same events will happen during long-term use.

If you have severe low glucose, high glucose that does not improve, ketones, or signs of DKA, follow the User Manual and your healthcare professional's instructions. Get medical help when needed.

4.3 Warnings and precautions

4.3.1 Warnings

- 1) Users, including patients, caregivers, guardians and other intended users, must receive professional training from healthcare professionals before operating the device.
- 2) A healthcare professional should establish the Insulin Patch Pump therapy plan and adjust insulin delivery settings based on treatment feedback (e.g., 4 daily fingertip blood glucose tests). Patients may operate the device once they have been adequately trained and their blood glucose patterns are sufficiently understood and stabilized.
- 3) Patients should maintain communication with healthcare professionals and adjust insulin delivery settings only as medically advised .
- 4) Patients must understand diabetes management, including adjusting bolus doses based on diet and managing hyperglycemia/hypoglycemia.
- 5) The instructions in the Instruction for Use are intended to support device operation only. They do not replace professional medical advice, diagnosis, or treatment.
- 6) Initiating therapy or modifying pump or APP settings without proper training and supervision may result in incorrect insulin delivery, potentially leading to hypoglycemia or hyperglycemia.
- 7) If insulin delivery is suspended, check the cause, test blood glucose manually, and take appropriate action.
- 8) Only use designated rapid-acting U-100 insulin; do not fill the pump with any other liquid. Never fill the pump with insulin that is expired, cloudy, or otherwise suspected to be compromised.
- 9) Do not administer insulin by another route(e.g., injections or inhaled insulin) while the pump is actively delivering insulin,as this may result in insulin stacking and hypoglycemia.
- 10) Do not introduce air bubbles when filling the pump reservoir.
- 11) Use only MicroTech Medical disposables specified for use with this system; third-party consumables may result in

inaccurate delivery or device malfunction.

12) Do not use the pump if you are sensitive or allergic to acrylic or medical adhesives, or if your skin is fragile or easily damaged.

13) Skin irritation or allergic reactions may occur at the device application sites. To minimize risk:

- Thoroughly clean and dry the skin before application.
- Regularly rotate application sites.
- Do not apply the device to damaged, irritated, or compromised skin (e.g., cuts, burns, or rashes).
- Ensure proper skin care at the infusion site.

14) This device is not intended for children under 2 years of age. Contact with the pump or adhesive patch may cause burns.

15) If the sterile packaging is compromised or opened for any reason other than intended use, do not use the product inside.

16) The skin surface temperature at the infusion site of the human body shall not exceed 43°C.

17) Surface temperature limits: Pump: $\leq 43^{\circ}\text{C}$ during use and charging.

18) If the APP disconnects or is lost, the pump will continue delivering preset basal rates (including automated basal adjustments, if applicable). Pressing the button on the side of the pump enables bolus insulin delivery.

19) If the APP is unavailable, disconnect the pump and follow your backup insulin plan and carry an insulin pen or other emergency insulin supplies.

20) Risk of hyperglycemia: Avoid setting the maximum insulin delivery too low. Parameter settings must align with individual medical conditions and professional guidance.

21) The Insulin Infusion Set component contains a needle and therefore presents a risk of infection or needlestick injury. Please dispose of the used components in accordance with local laws and regulations.

22) The insulin infusion set and reservoir are sterile, single-use components sterilized by ethylene oxide. Do not use sterile consumables if the packaging is damaged.

23) Do not use any part of the EquilS system (pump or APP) if you suspect physical damage after an unexpected event.

24) The shelf life of sterile consumables is 3 years. Do not use them after the expiration date.

25) Before inserting the subcutaneous infusion set, clean the infusion site area with an alcohol wipe to remove any oils or dirt.

26) Do not place the infusion set over skin folds, scars, induration/lipohypertrophy, the belt line, stretch marks, or within 2-3cm of the navel.

27) Prolonged use of the same infusion site may lead to subcutaneous nodules. Rotate the infusion site regularly to reduce the risk. The infusion site must be at least 7.5 cm away from the CGM sensor insertion site.

- 28) If the user is unable to replace the reservoir promptly after a “Reservoir Low!” alert , the low insulin alarm threshold may be adjusted according to individual needs.
- 29) Do not manually inject or infuse insulin when Auto Mode is active, or within 5 hours before starting Auto Mode. Otherwise, active insulin may not be estimated correctly, which may result in excessive insulin delivery and hypoglycemia. If insulin has been administered manually, wait 5 hours before starting Auto Mode.
- 30) Replace reservoir and infusion set every 72 hours.
- 31) In Auto Mode, bolus delivery only supports ordinary bolus, and it does not support extended bolus.
- 32) During meals, glucose measurements from the CGM system may be delayed, which can lead to inaccurate basal rate delivery in Auto Mode; therefore, manual bolus administration is required at this time.
- 33) In Auto Mode, the CGM system must not be unpaired or forcibly disconnected.
- 34) Individuals must remove all components of the device, including the Insulin Patch Pump and sensor, before undergoing Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. Additionally, the Controller should be placed outside the procedure room, as exposure during these procedures may cause damage to the components.

4.3.2 Precautions

- 1) Read this user manual carefully before using the device.
- 2) Update the PDA/APP time zone according to your healthcare provider’s guidance.
- 3) Adjustments to infusion status require the pump and PDA/APP to remain within communication range.
- 4) Do not use the device under oxygen-enriched conditions.
- 5) Avoid sources of electromagnetic interference; ensure Bluetooth communication remains unobstructed during use.
- 6) Operating temperature: 5–40°C. If the device is removed from storage at -40°C or 55°C, allow it to acclimate to room temperature for at least 30 minutes before use.
- 7) Avoid heat sources (for example, stoves) and high-moisture environments (for example, steam).
- 8) Operating humidity: 10–93% (non-condensing).
- 9) Operate strictly according to this user manual. MicroTech Medical will assist with issues but is not liable for misuse-related consequences.
- 10) Keep the device away from insects, pets, and children.
- 11) When not in use, store the device and its components out of children’s reach. Dispose of used consumables in accordance with local regulations.
- 12) Check device function periodically; contact your local distributor if technical support is needed.
- 13) If the device is stored for an extended period, charge the pump and PDA at least once every 6 months.

- 14) Clean the device every 3 days with water or low-concentration alcohol during active use.
- 15) Clean the device thoroughly before reuse by another patient.
- 16) Before using APP/PDA, users should be familiar with the basic operation of their mobile device. To prevent unauthorized access, enable a lock screen password and manage the device securely.
- 17) Back up data before performing software updates to reduce the risk of data loss.
- 18) Maintain the pump and PDA/APP within 2 meters to ensure reliable data transmission and command execution..
- 19) The device generates real-time alerts for abnormal conditions (refer to Section 16.1: Troubleshooting List for details).
- 20) Software updates other than those specifically described in this user guide should be performed only with manufacturer or distributor support.
- 21) Used, non-functional, or expired insulin pumps and PDA should be disposed of in accordance with local applicable laws and regulations.
- 22) Please discard the removed fill adapter into a medical sharps container and in accordance with the local laws and regulations.
- 23) If the Medical Power Supply does not work, the internal fuse may be damaged. Do not disassemble it. Contact the local distributor or replace it with a new charger.
- 24) Use only the Medical Power Supply and charging cable specified or provided by MicroTech Medical.
- 25) Before pairing the PDA/APP with a new pump, delete previous pump-related configuration parameters.
- 26) During charging, the white charging light on the top of PDA remains on. The green indicator light at the top indicates that the battery is fully charged. When the green indicator of the pump remains on, the pump battery is fully charged.
- 27) The PDA/APP supports multiple preset basal rate profiles, accommodating varying basal insulin requirements across different periods.
- 28) After a temporary basal rate infusion ends, the insulin pump automatically resumes standard basal rate delivery. The PDA/APP home screen displays the current temporary basal infusion status on the relevant interface.
- 29) Always monitor glucose levels closely when using any bolus or extended bolus feature. Before delivery, the most recent bolus information (time and dose) is displayed in a pop-up window to help avoid unintentional repeat dosing. Confirm this information carefully before proceed to conduct next bolus delivery.
- 30) On the PDA/APP extended bolus screen, the total dose is automatically divided into an immediate bolus and an extended bolus according to the selected ratio.
- 31) Do not modify Bolus Calculator settings without clinical supervision.
- 32) In Auto Mode, insulin delivery is automatically suspended if the user is experiencing hypoglycemia or is predicted to become hypoglycemic.

- 33) The pump housing has an IPX8 rating and is protected against immersion in water up to a depth of 2 meters (6.56 feet) for up to 30 minutes. Do not expose the pump to water beyond this rated depth or duration.
- 34) Avoid using portable radio-frequency equipment—including devices with external antennas—within 30 cm (12 inches) of any EquiS component. RF interference may disrupt communication between the pump and PDA/APP.
- 35) The sound pressure level of the audible alarm ranges from 50 dB to 85 dB.
- 36) Individuals with coagulation disorders or those receiving anticoagulant therapy should consult a healthcare professional before use and monitor the CGM sensor and infusion-set insertion sites for signs of persistent or significant bleeding.

5. Summary of clinical evaluation and post-market clinical follow-up

The EquiS system was studied in 101 adults with type 1 diabetes. Time in Range (TIR) is the percent of time glucose stays from 3.9 to 10.0 mmol/L. Average TIR rose from 63.721% in Manual Mode to 74.522% in Auto Mode. This was a rise of 10.802 percentage points. Time above and below the target range also fell in Auto Mode.

Another study included 129 children and teens aged 2 to 17 years. In Auto Mode, average TIR rose by 7.716 percentage points overall compared with Manual Mode. It rose by 8.517 points in children aged 2 to 6 years and by 7.567 points in those aged 7 to 17 years. Time above the target range fell. Time below 3.9 mmol/L also fell overall.

After CE marking, the manufacturer will collect more safety and performance data during routine use. A study in France will compare EquiS with another AID system. People in the study will be followed for up to one year.

6. Possible diagnostic or therapeutic alternatives

There are several ways to manage type 1 diabetes:

- Multiple daily insulin injections.
- Conventional insulin pump therapy.
- Insulin pumps used with continuous glucose monitoring.
- Systems that can stop insulin when glucose is low or predicted to become low.
- Other automated insulin delivery systems.

These options differ in how much insulin is automated, how often you make treatment decisions, what equipment you wear, and how much training you need.

AID systems can reduce some daily insulin decisions. You still need to respond to alarms, manage meals and bolus insulin, replace infusion and sensor parts, and follow your backup plan if the system cannot be used.

Your healthcare professional can explain the options and help you choose one that fits your needs.

7. Suggested training for users

Patients, caregivers, and guardians should be trained before using the system. Training should cover the main tasks for safe use. Learn how to set up and wear the pump, fill and replace the reservoir, insert and replace the infusion set, pair the pump and CGMS, and use the PDA or app. Training should also cover basal and bolus insulin, Auto Mode and Manual Mode, alarms, low or high glucose, emergencies, backup insulin, charging, cleaning, and safe disposal of used parts.

Ask your healthcare professional or technical support for help if you are unsure how to use the system. Get help if glucose readings are unexpected, alarms keep occurring, or the device may not be working. The manufacturer can provide technical support. Your healthcare professional should give medical advice and make treatment decisions.

8. Revision History

Revision	Date issued	Summary of Changes	NB validation
V1	29/06/2026	Initial Issue	Superseded during initial conformity assessment
V2	26/08/2026	Updated following first MDR technical documentation assessment	Pending NB validation