Declaration of Conformity

We

Aison Technologies AG
Wiesenstrasse 10A
CH – 8952 Schlieren
Swiss Registration Number (CHRN): CHRN-MF-20001872

declare that

the medical device(s):	aiSon™ Focus
Basic UDI-DI:	76499886994AT1NE
Intended Purpose:	The aiSon™ Focus is intended to be used by sonographers and can be used on any patient independent of age, weight, or other health conditions. It can be used on any ultrasound probe with a sensor window 8.0cm x 2.0cm or smaller. It is intended to • avoid misdiagnoses from compression of underlying structures (e.g., all pathological, superficial fluid collections), • avoid painful examinations for the patient (e.g., acute trauma with open or closed fractures, nerve lesions), • facilitate ultrasound-guided interventions that do not require sterile conditions, • increase patient comfort (e.g., babies, or if a patient shows resistance towards the generous usage of ultrasound coupling agent), • enable diagnoses in hard-to-reach areas of the patient's body (e.g., Achilles tendon, anterior neck region, fingers, toes, pelvic floor, eyes, ears). The aiSon™ Focus achieves its function by maximizing the contact area of the ultrasound probe with the patient's body to be examined. In addition, it is an adaptive ultrasound stand-off pad, which allows for a dynamic shift of the ultrasound image focus (point of highest image resolution). The shift can be achieved by increasing or decreasing the distance of the ultrasound probe to the body to be imaged by manually compressing or releasing

	the pad. It is intended for single-day multi-use on intact skin. It's intended to be used as an accessory to an ultrasound device to specifically and directly assist the medical functionality of the ultrasound device in terms of its intended purpose (please be referred to the Instructions For Use provided by the manufacturer of your ultrasound system).
Risk Class:	Class I
Rule (according to Annex VIII):	Rule 1

Meet(s) all the provisions of the medical device regulation (MDR) 2017/745, which apply to it.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

European Authorized Representative (EC-Rep):	Aison Technologies Poland Sp. Z o.o. Masarska 13/8 31-534, Krakow, Poland
Single Registration Number (SRN) EC-Rep:	as soon as available
Applied Common Specifications:	On the date of issue of this document, no relevant common specifications were available
Conformity Assessment Procedure:	**Annex IX** Chapter I, III and Section 4

This declaration is valid for the products placed on the market as of 04.03.2022.

Schlieren, 14.09.2022

Dr. Sophia Borowka, CEO

Signature 1: Dr. Sophia Borowka
09/14/2022 14:10:30 UTC

Article List

Article Number	Product Name / Registered Trade Name	Classification	Rule
001.001.001	aiSon™ FOCUS	Class I	Rule 1

4 References

4.1 Referenced Documents

[1] SOP-200 Design Development (V1)

5 Annex

5.1 Document History

Version	Author	Description of Changes
1	Sophia Borowka	- First version
2	Sophia Borowka	- Added CHRN Number
3	Jinesh Kallunkathariyil	- Added EC REP
4	Sophia Borowka	Updated product name (spelling) and design