

aiSon™ Focus & aiSon™ Focus Small product information

Product name	aiSon™ Focus	aiSon™ Focus Small
Article number	001.001.001	003.001.001
Short description	Adaptive ultrasound pad for all customary ultrasound probes	Adaptive ultrasound pad for all hockeystick ultrasound probes
Type	Non-sterile, disposable medical device	
Regulatory status	Class I (EU MDR), CE conform	
Compatibility	Compatible with all customary ultrasound probes with transducer sizes up to 8 cm x 2 cm	Compatible with all customary ultrasound probes with transducer sizes up to 4.5 cm x 1.5 cm
	<ul style="list-style-type: none"> Usable in combination with sterile probe covers Usable with ultrasound gel, disinfectant (non-pyridine), water, oil, etc. as coupling fluid 	
Shelf life	12 months	
Quantity	25 units/box	
Packaging	<ul style="list-style-type: none"> Box: 28.6 x 19 x 19 cm Unit: 19 x 8.5 x 0.3 cm 	
Weight	10 g/unit	
Ingredients	<ul style="list-style-type: none"> Recyclable plastic & water-based filling Free of latex & phthalates 	
Storage conditions	Room temperature	
Disposal	Regular recycling bin	
UDI/GTIN code	07649988699412	07649988699429
ECLASS no. (v12.0)	34-55-09-92: diagnostic imaging device (ultrasonic, accessories)	
HS code	9018.1200: accessory to ultrasonic scanning apparatus	
eIFU	https://www.aisontechnologies.com/aisonfocus-ifu	

Manufacturer information

Owner & manufacturer	Aison Technologies AG Postfach 8021 Zurich 1 Switzerland VAT no.: CHE-255.058.642
UDI-ID	76499886994AT1NE
CHRN:	CHRN-MF-20001872
GLN:	7649988699405
EC-REP	Aison Technologies Poland Sp. z o.o. Wielicka 25, pok. 115 33-332 Krakow Poland VAT no.: PL6751761895
SRN:	As soon as available
Quality management certification	ISO 13485:2016 Issued 11/03/2022, expires 10/03/2025