



20000487/7.0

**EU DECLARATION OF CONFORMITY
STED-022/ALUETTA**

Document reference
20532747/V1.0

Manufacturer:
Ares Trading SA
Zone industrielle de l'Ouriettaz
1170 Aubonne
Switzerland
SRN: Not issued yet

Authorised Representative:
Merck Healthcare KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany
SRN: DE-AR-000007181

EN

EU DECLARATION OF CONFORMITY

Product Name:	Model:	Catalogue Number REF	UDI-DI	Basic UDI-DI
aluetta pen	6 mg	Refer to Table in Annex		4054839aluettaHJ
aluetta pcn	12 mg			
aluetta pen	20 mg			
Description:	Pen injector for the administration of Saizen® (GMDN 45771, Cartridge-accepting autoinjector, mechanical)			

We Ares Trading SA, Zone industrielle de l'Ouriettaz, 1170 Aubonne, Switzerland, hereby declare under our sole responsibility that the above listed products are in conformity with the following regulations:

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The product is classified as **class I** medical device according to rules 1 and 2 of Annex VIII with **measuring function** according to MEDDEV 2.1/5.
The conformity assessment procedure per **Annex IX** based on a quality management system and after drawing up the technical documentation was followed.
The conformity assessment is supported by **EC certificate** MDR 736344 R000 with expiry date 2026-03-29 delivered by Notified Body BSI (British Standard Institute), identification number 2797.

The following standards were used to support the conformity of the product:

- 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
- IEC 62366-1:2015. Medical devices - Application of usability engineering to medical devices
- ISO 11608-1:2014. Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems
- ISO 11608-2:2012. Needle-based injection systems for medical use - Requirements and test methods -- Part 2: Needles
- ISO 11608-3:2012. Needle-based injection systems for medical use - Requirements and test methods Part 3: Finished containers
- ISO 10993-1:2018. Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process





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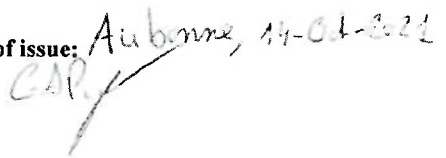
EN ISO 1041:2008 + A1:2013. Information supplied by the manufacturer of medical devices.

EN ISO 15223-1:2016. Medical Devices – Symbols to be used with Medical Devices Labels, Labelling, And Information to be Supplied - Part 1: General Requirements


This Declaration of Conformity is supported by the technical documentation referenced as STED-022 (ID#20493300).

Signed for and on behalf of Ares Trading SA

Name: Claude-Alain PIGUET
Function: Head of Connected Health & Devices Quality
Authorised Representative of Ares Trading SA

Place and date of issue: Aubonne, 14-Oct-2021
Signature: 

Name: Clorinde HIRT
Function: Head of Device Quality System
Authorised Representative of Ares Trading SA

Place and date of issue: Aubonne, 14-Oct-2021
Signature: 



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Annex. Table of Products covered by the EU Declaration of Conformity

Catalogue Number REF	UDI-DI	Catalogue Description
U1222214	04054839644085	ALUETTA PEN 6MG (1)-EMD-CAN
U1222215	04065266531534	ALUETTA PEN 12MG (1)-EMD-CAN
U1222216	04054839644092	ALUETTA PEN 20MG (1)-EMD-CAN
U1222263	04065266531541	ALUETTA PEN 6MG (1)-EMD-CIS
U1222264	04065266531558	ALUETTA PEN 12MG (1)-EMD-CIS
U1222265	04065266531565	ALUETTA PEN 20MG (1)-EMD-CIS
U1222272	04065266531503	ALUETTA PEN 6MG (1)-EMD-ME2
U1222273	04065266531510	ALUETTA PEN 12MG (1)-EMD-ME2
U1222274	04065266531527	ALUETTA PEN 20MG (1)-EMD-ME2
U1222291	04065266536454	ALUETTA PEN 6MG (1)-MS-APAC2
U1222292	04065266536508	ALUETTA PEN 12MG (1)-MS-APAC2
U1222293	04065266536515	ALUETTA PEN 20MG (1)-MS-APAC2
U1222294	04065266536522	ALUETTA PEN 6MG (1)-MS-IDN2
U1222295	04065266536577	ALUETTA PEN 12MG (1)-MS-IDN2
U1222296	04065266536584	ALUETTA PEN 20MG (1)-MS-IDN2
U1222297	04065266536591	ALUETTA PEN 6MG (1)-MS-VNM2
U1222298	04065266536607	ALUETTA PEN 12MG (1)-MS-VNM2
U1222299	04065266536614	ALUETTA PEN 20MG (1)-MS-VNM2
U122220A	04065266536621	ALUETTA PEN 6MG (1)-MS-CEE4
U122220B	04065266536638	ALUETTA PEN 12MG (1)-MS-CEE4
U122220C	04065266536645	ALUETTA PEN 20MG (1)-MS-CEE4
U122220D	04065266536652	ALUETTA PEN 6MG (1)-MS-KOR2





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U122220E	04065266536669	ALUETTA PEN 12MG (1)-MS-KOR2
U122220F	04065266536713	ALUETTA PEN 20MG (1)-MS-KOR2
U122220G	04065266536720	ALUETTA PEN 6MG (1)-MS-CENTRO2
U122220H	04065266536737	ALUETTA PEN 12MG (1)-MS-CENTRO2
U122220I	04065266536744	ALUETTA PEN 20MG (1)-MS-CENTRO2
U122220J	04065266536751	ALUETTA PEN 6MG (1)-MS-BRA2
U122220K	04065266536768	ALUETTA PEN 12MG (1)-MS-BRA2
U122220L	04065266536775	ALUETTA PEN 20MG (1)-MS-BRA2
U122220M	04065266536782	ALUETTA PEN 6MG (1)-MS-PER2
U122220N	04065266536799	ALUETTA PEN 12MG (1)-MS-PER2
U122220O	04065266536805	ALUETTA PEN 20MG (1)-MS-PER2
U122220P	04065266536812	ALUETTA PEN 6MG (1)-MS-ME3
U122220Q	04065266536829	ALUETTA PEN 12MG (1)-MS-ME3
U122220R	04065266536836	ALUETTA PEN 20MG (1)-MS-ME3
U122220S	04065266536843	ALUETTA PEN 6MG (1)-MS-GR-TR2
U122220T	04065266536850	ALUETTA PEN 12MG (1)-MS-GR-TR2
U122220U	04065266536867	ALUETTA PEN 20MG (1)-MS-GR-TR2
U122220V	04065266536874	ALUETTA PEN 6MG (1)-MS-ENG3
U122220W	04065266536881	ALUETTA PEN 12MG (1)-MS-ENG3
U122220X	04065266536898	ALUETTA PEN 20MG (1)-MS-ENG3
U122220Y	04065266536904	ALUETTA PEN 6MG (1)-MS-WEU4
U122220Z	04065266536911	ALUETTA PEN 12MG (1)-MS-WEU4
U122221A	04065266536928	ALUETTA PEN 20MG (1)-MS-WEU4





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U122221B	04065266536935	ALUETTA PEN 6MG (1)-MS-WEU5
U122221C	04065266536997	ALUETTA PEN 12MG (1)-MS-WEU5
U122221D	04065266537000	ALUETTA PEN 20MG (1)-MS-WEU5
U122221E	04065266537017	ALUETTA PEN 6MG (1)-MS-LATAM3
U122221F	04065266537024	ALUETTA PEN 12MG (1)-MS-LATAM3
U122221G	04065266537031	ALLUETTA PEN 20MG (1)-MS-LATAM3
U122221H	04065266537048	ALUETTA PEN 6MG (1)-MS-SEU2
U122221I	04065266537055	ALUETTA PEN 12MG (1)-MS-SEU2
U122221J	04065266537062	ALUETTA PEN 20MG (1)-MS-SEU2
U122221K	04065266537079	ALUETTA PEN 6MG (1)-MS-IND2
U122221L	04065266537086	ALUETTA PEN 12MG (1)-MS-IND2
U122221M	04065266537093	ALUETTA PEN 20MG (1)-MS-IND2
U122221N	04065266536058	ALUETTA PEN 6MG (1)-MS-THA2
U122221O	04065266536065	ALUETTA PEN 12MG (1)-MS-THA2
U122221P	04065266536072	ALUETTA PEN 20MG (1)-MS-THA2
U122221Q	04065266536089	ALUETTA PEN 6MG (1)-MS-CEE5
U122221R	04065266536096	ALUETTA PEN 12MG (1)-MS-CEE5
U122221S	04065266538304	ALUETTA PEN 20MG (1)-MS-CEE5