



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Etkon GmbH
Lochhamer Schlag 6, 82166 Gräfelfing,
Germany
SRN: DE-AR-000009335

Conformity Assessment

Conformity Assessment Procedure
Annex II+III, IV of Regulation (EU) 2017/745

Product Information

Product name: Intraoral Scanner
Model: S300W
Brand name: Alliedstar Sensa
EMDN: Q010207
GMDN: 63669
Basic UDI-DI : 697399344alliedstar01SL
Classification: Class I, according to Rule 13 and Rule 5, Annex VIII, Regulation (EU) 2017/745
Classification of Components/Accessories:
See Table 1

Intended purpose: The Intraoral Scanner is a digital optical scanning device used to obtain digital impressions of hard and soft tissues such as teeth, gingival, and mucous membrane by means of oral scanning, for oral restoration and orthodontic treatment of malocclusion.

Manufacturer

Name: Alliedstar Medical Equipment Co., Ltd.
Address: No.1-4, Floor 3, Unit 2, Building 3, No.222,
West third section, Waihuan Road, Yanjiang District,
Ziyang, 641300, Sichuan, P.R. China
SRN: CN-MF-000008845

Declaration

This declaration of conformity is issued under the sole responsibility of the Legal Manufacturer. We, the Legal Manufacturer, hereby declare that the above specified product complies with the following European Regulation and Directives with amendments, and their relevant transposition into national laws of the member states into which we place the device:

Regulation (EU) 2017/745 on medical devices
Directive 2014/53/EU Radio Equipment Directive
Directive 2011/65/EU RoHS Directive

List of Applied Standards

Harmonized Standards and Common Specifications used for conformity assessment are listed in the Technical Documentation.

DocuSigned by:

Signature: BD1F5F4A9ECE42F... Date: 2025/04/15
Name: Zheng Shi Place: Ziyang / China
Position: PRRC

Tabel 1 Classification of Intraoral Scanner and Components/Accessories
according to Annex VIII of the MDR

Product	Model	Classification	GMDN	REF	Remark
Alliedstar Sensa Intraoral Scanner	S300W	Class I, Rule 5&13	63669	6583440	Advanced
Alliedstar Sensa Intraoral Scanner	S300W	Class I, Rule 5&13	63669	6583318	Demo
Alliedstar Sensa Intraoral Scanner	S300W	Class I, Rule 5&13	63669	6583441	Education
Alliedstar Sensa Handpiece	/	Class I, Rule 13	63669	6583397	/
Alliedstar Sensa Charging Holder	CHR 300W	Class I, Rule 13	63669	6583319	/
Alliedstar Sensa Scanner Tip (2pcs)	TP301	Class I, Rule 5	63669	6583320	/

