



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: AS 100, AS 200E, AS 260, AS 260a
Brand name: Alliedstar
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 Technicaocumentation.

DocuSigned by:
Signature: *Zheng Shi* Date: 2024/6/6
Name: Zheng Shi Place: Ziyang / China
Position: PRRC

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

Product	Model	Classification	GMDN	REF
Intraoral Scanner	AS 100	Class I, Rule 5& 13	63669	6583169
Intraoral Scanner	AS 100	Class I, Rule 5& 13	63669	6583174
Intraoral Scanner	AS 100	Class I, Rule 5& 13	63669	6583200
Intraoral Scanner	AS 100	Class I, Rule 5& 13	63669	6583399
AS 100 Handpiece	/	Class I, Rule 13	63669	6583181
AS 100 Holder	/	Class I, Rule 1	63669	6583182
Scanner Tip (L x 2pcs)	TP102	Class I, Rule 5	63669	6583210
Scanner Tip (S x 2pcs)	TP103	Class I, Rule 5	63669	6583211
Scanner Tip (L x 2pcs)	TP104	Class I, Rule 5	63669	6583300
Intraoral Scanner	AS 200E	Class I, Rule 5&13	63669	6583202
AS 200E Handpiece	/	Class I, Rule 13	63669	6583217
AS 200E Charging Holder	CHR 200E	Class I, Rule 13	63669	6583203
Scanner Tip (L x 2pcs)	TP202	Class I, Rule 5	63669	6583226
Scanner Tip (S x 2pcs)	TP203	Class I, Rule 5	63669	6583225
Scanner Tip (L x 2pcs)	TP204	Class I, Rule 5	63669	6583296
AS 200E Battery (2pcs)	Li-18650-3.6V 3500mAh-PCM-Cap	Class I, Rule 13	63669	6583221
AS 200E Battery(2pcs) x 20	Li-18650-3.6V 3500mAh-PCM-Cap	Class I, Rule 13	63669	6583282
Intraoral Scanner	AS 260	Class I, Rule 5&13	63669	6583207
AS 260 Handpiece	/	Class I, Rule 13	63669	6583243
Desktop Holder	/	Class I, Rule 1	63669	6583246
Wall Mount Holder	/	Class I, Rule 1	63669	6583245
AS 260 USB Cable	/	Class I, Rule 13	63669	6583244
Scanner Tip (L x 2pcs)	TP202	Class I, Rule 5	63669	6583226
Scanner Tip (S x 2pcs)	TP203	Class I, Rule 5	63669	6583225
Scanner Tip (L x 2pcs)	TP204	Class I, Rule 5	63669	6583296
Intraoral Scanner	AS 260a	Class I, Rule 5&13	63669	6583391
AS 260a Handpiece	/	Class I, Rule 13	63669	6583393
Desktop Holder	/	Class I, Rule 1	63669	6583396
USB Cabel	/	Class I, Rule 13	63669	6583416
Scanner Tip (L x 2pcs)	TP202	Class I, Rule 5	63669	6583226
Scanner Tip (L x 2pcs)	TP204	Class I, Rule 5	63669	6583296