



Document Number : INTCOAH-CE-DC-SSV-001

Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Anhui Intco Medical Products Co., Ltd.**

Address: **No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province**

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands**

Declares that the MDR described hereafter

Product name and model:

Vasco® Vinyl Sensitive Exam Gloves

EMDN code: T01020299

Model: S /M /L /XL

Product Code: Please refer to the attachment for more details.

Basic UDI-DI: 697306977SynmaxWW **SRN:** CN-MF-000002356

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Anhui Intco Medical Products Co., Ltd.

Classification: Class I for medical device(rule 1 & rule 5, Annex VIII MDR), Cat III for PPE

We declare that the production of medical devices as specified above is carried out in

accordance with MDR EU 2017/745 and PPE regulation EU 2016/425

MDR Harmonized Standard: EN ISO 13485:2016; EN 14971:2019; ISO 20417:2021; EN 15223-1:2021; EN 455-1:2020+A2:2024; EN 455-2:2024; EN 455-3:2023; EN 455-4:2009; EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2023; EN ISO 10993-11:2018; EN ISO10993-23:2021.

PPE Harmonized Standard: EN ISO 21420:2020+A1:2024, EN ISO 374-1:2016 +A1:2018, EN374-4:2019, EN ISO 374-5:2016

The notified body SATRA Technology Europe Ltd (Number: 2777) performed:

- EU type-examination Certificate (Module B), certificate number: 2777/15661-02/E00-00
- Module D certificate

We agree to develop, implement and maintain a documented post-production monitoring process.

Anhui 2025-11-18

Place , date

Wang Yazhou

王亚州

Quality Manager

Legally binding signature, Function

Anlage 1 /Annex 1:

Markenname / Brand name: Vasco® Vinyl Sensitive
Produktgruppe/ product group: SYNMAX VINYL® Exam Gloves
Basis-UDI-DI: 697306977SynmaxWW

Vasco® Vinyl Sensitive

Produktname <i>product name</i>	Verpackungs- größe <i>Packaging size</i>	Handschuh- größe <i>size</i>	Artikel- nummer <i>item number</i>	Risiko- klasse <i>Risk class</i>	Regel <i>rule</i>	EMDN	Kategorie <i>category</i>
Vasco® Vinyl Sensitive	100pcs/box	S	6091520	I	1 & 5	T01020299	III
		M	6091530	I	1 & 5	T01020299	III
		L	6091540	I	1 & 5	T01020299	III
		XL	6091550	I	1 & 5	T01020299	III