


KDL	Document name	EU Declaration of conformity	Document No.:	ZKDL/TECH-MDR-04/00	
	Product name	Disposable Needles	Version	A/7	Page 2 of 3

EU Declaration of conformity	
Manufacturer:	Zhejiang kindly medical devices Co., Ltd. No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80,20537 Hamburg Germany SRN: DE-AR-000000001
Device name:	Disposable Needles
Device Model Number:	1. Variant 1: Disposable Needles (Hypodermic Needles) Gauge 14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G 2. Variant 2: Safety Needles (Type 1) Safety Needles: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G 3. Variant 3: Safety Needles (Type 2) Safety Needles: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G 4. Variant 4: Safety Needles (Type 3) Safety Needles: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G
Device Intended purpose	Disposable Needles (Hypodermic Needles) is intended to inject or withdraw fluids from primarily the human body
Basic UDI-DI:	Normal type: 69230334202002a00401LY Safety type: 69230334202002a00402M2
Risk class:	II a, Rule 6
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Conformity assessment Route:	MDR Annex IX, chapter I+III
References	Q/KDL 031:2020,ISO 7864:2016,ISO 9626:2016,ISO 6009:2016,MEDDEV.2.7.1 Rev.4,EN 556-1:2024,EN 62366-1:2015/A1:2020,EN ISO 15223-1:2021/Amd 1:2025,EN ISO 20417:2021,EN ISO 80369-7:2021,EN ISO 11135:2014/A1:2019,EN ISO 11737-1:2018/2021,EN ISO 11737-2:2020,EN ISO 11138-1:2017,EN ISO 11138-2:2017,EN ISO 11607-1:2020/A1:2023,EN ISO 11607-2:2020/A1:2023,EN ISO 13485:2016/A11:2021 ,EN 17141:2020,EN ISO 14644-1:2015,EN ISO 14644-2:2015,EN ISO 14644-3:2019,EN ISO 14971:2019/A11:2021,EN ISO 10993-1:2025,EN ISO 10993-4:2017/A1:2025,EN ISO 10993-5:2009/A11:2025,EN ISO 10993-7:2008/A1:2022,EN ISO 10993-10:2023,EN ISO 10993-11:2018,ASTM F1980:2021, EN ISO 23908:2025
Statement	We hereby declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer, the products mentioned above are in conformity with the medical device Regulation, all supporting documentations are retained under the premises of the manufacturer.
Notified body	Name: TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 München · Germany

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NB Identification number	0123
Manufacturer SRN:	CN-MF-000007594
(EC) Certificate(s)	G15 036336 0061 Rev. 00
Expire date of the Certificate	2031-04-14
Start of CE-marking:	2021-04-15
Place,Date of declaration	Wenzhou, 2026-04-22
Signature:	
Name:	LI Suhua
Position:	QA manager
Rev.20260422	