

EU DECLARATION OF CONFORMITY

According to ANNEX IV of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Wuxi Jiajian Medical Instrument Co., Ltd.

Trademark: /

Product Name: Sterile Acupuncture Needles

Model: Specification: Needle body Diameter x Needle body Length
Needle body Diameter: $\Phi 0.13\text{mm}-\Phi 1.00\text{mm}$, diameter interval 0.01mm
Needle body Length: 7mm-150mm, length interval 1mm

SRN: CN-MF-000012006

European Representative: Caretechion GmbH

SRN: DE-AR-000005946

CND Code: A019002

Intended use:	It is used by the professional acupuncturists, who use the sterile acupuncture needles on the human body to stimulate the body to relieve pain.
Basic UDI:	Sterile acupuncture needle with metal handle (sterilized with EO): 697201171C0000001GB Sterile acupuncture needle with metal handle (sterilized with Gamma): 697201171C0000002GD Sterile acupuncture needle with plastic handle (sterilized with EO): 697201171C0000003GF

Classification acc. to MDR Ax. VIII:

IIa

CE Technical File Sterile Acupuncture Needles	File No: JJ-CE-01-2.5
	Rev. No: A6

**Conformity Assessment
Procedure:**

Annex IX Chapter I, Section 2 and 3, MDR (2017/745)

CE Certificate No.:

HZ 2140536-1

**Name and ID of the Notified
Body:**

Name: TÜV Rheinland LGA Products GmbH

Address: Tillystraße 2, 90431 Nürnberg, Germany


(Notified body number: 0197)

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Place: Wuxi Position: general manager

Name: Wang Wenqing

Date: 2023.06.07

Signature: 

Attachment 1:

No.	Description	Basis UDI
A012186	Tewa PB Type	6972011710992
A000693	Tewa PB Type	6972011711005
A000694	Tewa PB Type	6972011714389
A012187	Tewa PB Type	6972011714396
A000695	Tewa PB Type	6972011715416
A000696	Tewa PB Type	6972011715461
A000697	Tewa PB Type	6972011715478
A000698	Tewa PB Type	6972011715485
A000699	Tewa PB Type	6972011715492
A000700	Tewa PB Type	6972011715508
A000701	Tewa PB Type	6972011711913
A000702	Tewa PB Type	6972011715430
A000703	Tewa PB Type	6972011715447
A000704	Tewa PB Type	6972011711920
A000705	Tewa PB Type	6972011715454
A000706	Tewa PB Type	6972011711937
A000707	Tewa PB Type	6972011711944
A000708	Tewa PB Type	6972011711951
A012183	Tewa CB Type	6972011710305
A000365	Tewa CB Type	6972011710312
A000366	Tewa CB Type	6972011710329
A012184	Tewa CB Type	6972011710336
A000367	Tewa CB Type	6972011710343
A000368	Tewa CB Type	6972011710350
A012185	Tewa CB Type	6972011710367
A000369	Tewa CB Type	6972011710374
A000370	Tewa CB Type	6972011710381
A000371	Tewa CB Type	6972011710398
A000372	Tewa CB Type	6972011710404
A000373	Tewa CB Type	6972011710411
A000374	Tewa CB Type	6972011710428
A000375	Tewa CB Type	6972011710435
A000376	Tewa CB Type	6972011710442
A000377	Tewa CB Type	6972011710459
A000378	Tewa CB Type	6972011710466
A000379	Tewa CB Type	6972011710473
A000380	Tewa CB Type	6972011710480
A000381	Tewa CB Type	6972011710497
A000382	Tewa CB Type	6972011710503
A000383	Tewa CB Type	6972011710510
A000384	Tewa CB Type	6972011710527
A000386	Tewa CB Type	6972011710534
A000387	Tewa CB Type	6972011710541
A000418	Tewa CB Type	6972011710169
A000420	Tewa CB Type	6972011710176
A000421	Tewa CB Type	6972011710183
A000422	Tewa CB Type	6972011710190
A000424	Tewa CB Type	6972011710206
A000425	Tewa CB Type	6972011710213
A00460	Tewa CJ Type	6972011711968
A00464	Tewa CJ Type	6972011710268

No.	Description	Basis UDI
A00465	Tewa CJ Type	6972011710275
A00466	Tewa CJ Type	6972011710282
A00469	Tewa CJ Type	6972011710299
A000436	Tewa CJ Type	6972011710787
A000437	Tewa CJ Type	6972011710794
A000438	Tewa CJ Type	6972011710800
A000439	Tewa CJ Type	6972011710817
A000440	Tewa CJ Type	6972011710824
A000441	Tewa CJ Type	6972011710831
A000442	Tewa CJ Type	6972011710848
A000443	Tewa CJ Type	6972011710855
A000444	Tewa CJ Type	6972011710862
A000445	Tewa CJ Type	6972011710879
A000446	Tewa CJ Type	6972011710886
A000447	Tewa CJ Type	6972011710893
A000448	Tewa CJ Type	6972011710909
A000449	Tewa CJ Type	6972011710916
A000450	Tewa CJ Type	6972011710923
A000452	Tewa CJ Type	6972011710930
A000453	Tewa CJ Type	6972011710947
A000454	Tewa CJ Type	6972011710954
A011557	Tewa CJ Type	6972011710961
A000457	Tewa CJ Type	6972011710978
A000458	Tewa CJ Type	6972011710985
A000430	Tewa 5CB Type	6972011710220
A000431	Tewa 5CB Type	6972011710237
A000432	Tewa 5CB Type	6972011710244
A000434	Tewa 5CB Type	6972011710251
A012181	Tewa 5CB Type	6972011710558
A012182	Tewa 5CB Type	6972011710565
A000389	Tewa 5CB Type	6972011710572
A000390	Tewa 5CB Type	6972011710589
A000391	Tewa 5CB Type	6972011710596
A000392	Tewa 5CB Type	6972011710602
A000393	Tewa 5CB Type	6972011710619
A000394	Tewa 5CB Type	6972011710626
A000395	Tewa 5CB Type	6972011710633
A000396	Tewa 5CB Type	6972011710640
A000397	Tewa 5CB Type	6972011710657
A000398	Tewa 5CB Type	6972011710664
A000399	Tewa 5CB Type	6972011710671
A000400	Tewa 5CB Type	6972011710688
A000401	Tewa 5CB Type	6972011710695
A000402	Tewa 5CB Type	6972011710701
A000403	Tewa 5CB Type	6972011710718
A000404	Tewa 5CB Type	6972011710725
A000405	Tewa 5CB Type	6972011710732
A000406	Tewa 5CB Type	6972011710749
A000407	Tewa 5CB Type	6972011710756
A000408	Tewa 5CB Type	6972011710763
A000409	Tewa 5CB Type	6972011710770

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / **Maanshan Bond Medical Instruments Co., Ltd.**
Name and address of the manufacturer: / **Meishan road, Maanshan Economic & Technology**
Nom et adresse du fabricant: / **Development Zone, Anhui Province 243041, P.R. China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Disposable Acupuncture needles** **UMDNS-Code: 12-730**
the medical device: /
le dispositif médical: /
il dispositivo medico: **Attachment 1**

der Klasse: / **Class IIa**
of class: /
de la classe: /
di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /
meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Directive 93/42/EEC Annex V**
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Registrier-Nr.: / **Certificate No.: DD 60146214 0001**
Registration No.: / **Issue date: 2020-03-19**
N°d'enregistrement: / **Expiry date: 2024-05-26**
Numero di registrazione:

Benannte Stelle: / **TÜV Rheinland LGA Products GmbH**
Notified Body: / **Tillystraße 2**
Organisme notifié: / **90431 Nürnberg**
Organismo notificato: **Deutschland**
CE 0197

Maanshan China 2020-04-01
Ort, Datum / Place, date /
Lieu, date / Luogo, data

GM: 王伟春
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Attachment 1:

No.	Description	Basis UDI
A000346	asia-med Special	04251282514914
A000355	asiamed Standard	04251282514921
A000552	asiamed Dauernadeln Press Tack	04251282515010
A000560	TeWa ID-Type	04251282515034
A000590	asiamed Gold Akupunktornadeln	04251282515041
A000593	asiamed Silver Akupunktornadeln	04251282515058
A000623	TeWa Gold-Type	04251282515065
A000646	asiamed s needle B-Type	04251282515072
A000673	asiamed s needle J-Type Place N' Press	04251282515089
A000692	TeWa PB-Type	04251282515096
A000709	TeWa PJ-Type	04251282515102
A000724	TeWa DPB-Type Detox	04251282515119
A000763	asia-med Special+	04251282515126
A000768	TeWa JJ-Type	04251282515133
A000781	TeWa JB-Type	04251282515140
A000786	TeWa 5JB-Type Speed Pak	04251282515157
A000799	TeWa KJ-Type	04251282515164
A000803	TeWa KB-Type	04251282515171
A000884	TeWa 5KB-Type Speed Pak	04251282515188