DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	SHANGHAI MEKON MEDICAL DEVICES CO., LTD.. 526, NO. 697-3 LINGSHI ROAD 200072 SHANGHAI CHINA
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg GERMANY
MEDICAL DEVICE:	DISPOSABLE INSULIN PEN NEEDLE：28G 29G 30G 31G 32G 33G
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 6*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX V*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARTION OF CONFORMITY

NOTIFIED BODY:	TÜV RHEINLAND LGA PRODUCTS GMBH TILLYSTRAßE 2 90431 NÜRNBERG
IDENTIFICATION NUMBER	CE 0197
(EC) CERTIFICATE(S):	DD 60149768 0001

Valid until: 2024-05-26

PLACE, DATE OF DECLARATION: Shanghai 2021-04-30

SIGNATURE: *POSITION: GENERAL MANAGER*