HINDUSTAN SYRINGES
& MEDICAL DEVICES LTD
MANUFACTURERS OF CE MARKED
STERILE MEDICAL DISPOSABLES

Version: 04
Date : 16/05/2019

EU Declaration of Conformity

Declaration of Conformity

for

- Hypodermic Syringes – Disposable/Auto Disable
- Insulin Syringes
- Needles- Hypodermic/Blood Collection
- Scalp Vein Infusion /Blood Collection Sets
- IV Cannula (Catheter) with/without S.I.P.Clip
- Pen Needles

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Hypodermic Syringes- Disposable/Auto Disable Insulin Syringes Hypodermic Needles Blood Collection Needles Scalp Vein Infusion Sets Blood Collection Sets I.V. Cannula (Catheter) Pen Needles
Legal Manufacturer:	HINDUSTAN SYRINGES & MEDICAL DEVICES LTD. 174, 178/25, BALLABGARH, FARIDABAD -121004, INDIA
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	As per Appendix II (This document) – Product Listing/Schedule
MDD Classification:	Class IIa
Notified Body / EC Certificate :	• PCBC (Polish Centre for Testing and Certification) identification number 1434 • EC Certificate Number 1434-MDD-243/2019 Validity : from 26/04/2019 to 27/06/2022
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance (excluding section 4) as per Annexure II European Council Directive 93/42/EEC as amended by 2007/47/EC

Name Rajiv Nath **Position** Managing Director

Signed **Date** 16/05/2019

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number (Product List)	Description/Name	Intended Use
Ref. Doc. # QS 07 07 00 29	Hypodermic Syringes Disposable/Auto Disable	for Injection / Aspiration of fluids.
Ref. Doc. # QS 07 07 00 29	Insulin Syringes	for Injection of insulin to patient with diabetic.
Ref. Doc. # QS 07 05 00 46	Hypodermic Needles	for Hypodermic / Dermal / Interadermal / Intravescular / Intramauscular Injection
Ref. Doc. # QS 07 07 00 44	Blood Collection Needles	for Blood specimen collection
Ref. Doc. # QS 07 07 00 44	Scalp Vein Infusion Sets / Blood Collection Sets	for Infusion / Drug delivery / Blood sampling
Ref. Doc. # QS 07 07 00 43	IV Cannula (Catheter) with/without S.I.P.Clip	for Intravenus / Intravascular access for short term peripheral Cannulation
Ref. Doc. # QS 07 00 00 170	Pen Needles	to be used with insulin injector for injecting insulin to patient with diabetic

Version History

Version	Compiled by	Date	Description
04	P.K. Sharma	16/05/2019	1. Change in Notified Body **from** UL International UK Ltd. **to** PCBC due to Brexit. 2. Change in EU Authorised Representative **from** HMD HEALTHCARE LIMITED Pure Offices, Plato Close Warwick CV34 6WE (U.K.) **to** Advena Ltd. Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta

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