DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42 EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Manufacturer:

SHENZHEN ANTMED CO.,LTD

Add: 18 Jinhui Ave., Pingshan New District, Shenzhen,

518122, China

HIGH PRESSURE SYRINGE

CM-60, CM-65, CM-100, CM-115, CM-125, CM-130, CM-

MEDICAL DEVICE: 150, CM-190, CM-200, CM-60/60, CM-60/125, CM-65/65,

CM-65/115, CM-100/100, CM-100/200, CM-130/200, CM-

150/150, CM-190/190, CM-200/200

CLASSIFICATION:

SPECIFICATION:

CLASS IIa, RULE 2

CONFORMITY ASSESSMENT ROUTE: ANNEX II excluding (4)

We, the manufacturer, here with declare under our sole responsibility 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.

(WE, AS MANFACTURER, ARE EXCLUSIVELY RESPONSIPLE FOR THE DECLARATION OF CONFORMITY.)

NOTIFIED BODY:

TÜV SÜD Product service GmbH

Ridlerstr 65, 80339 München, Germany

IDENTION NUMBER:

C €₀₁₂₃

(EC)CERTIFICATE(S):

G1 004593 0002 Rev.01

VALID UNTIL:

2028-12-30

EC REP

MedNet EC-REP GmbH,

European Representative:

Borkstrasse 10, 48163 Münster, Germany

START of CE-MARKING:

2005-11-20

PLACE, DATE OF DECLARATION:

SHENZHEN, 2024-01-10

SIGNATURE

NAME: MR. FENG, GAO

POSITION: PRRC