

DECLARATION OF CONFORMITY

Doc ID: ANT/CE-HPS-07



MANUFACTURER:

SHENZHEN ANTMED CO.,LTD.

18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, CHINA

SRN OF THE MANUFACTURER:

CN-MF-000029659

MEDICAL DEVICE:

High Pressure Syringe

MODEL:

CM-60, CM-60/60, CM-65, CM-65/65, CM-100, CM-100/100, CM-65/115, CM-125, CM-130, CM-140, CM-150, CM-190, CM-200, CM-130/200, CM-100/200, CM-60/100, CM-60/200, CM-190/190, CM-200/200

BASIC UDI-DI:

69457644HPS0000001HG

CLASSIFICATION - ANNEX IX:

Class IIa, Rule 2

CONFORMITY ASSESSMENT ROUTE:

Annex IX of MDR on (EU) 2017/745

WE, THE MANUFACTURER, HERE WITH DECLARE ON OUR OWN RESPONSIBILITY THAT THE MEDICAL DEVICE: MEET ALL THE PROVISIONS OF THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICE, WHICH APPLY TO IT. EVERY ARTICLE WE SELL IS COVERED BY A TECHNICAL DOCUMENTATION. TECHNICAL DOCUMENTATION ARE PROVIDED TO THE EUROPEAN AUTHORIZED REPRESENTATIVE AND KEPT UP TO DATE BY US.

NOTIFIED BODY:

**TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY**

IDENTIFICATION NUMBER:

CE 0123

(EC) CERTIFICATE(S):

G10 004593 0011 REV. 00

EXP. DATE:

2029-02-05



EC-REP:

**MedNet EC-Rep C IIb GmbH
Borkstrasse 10, 48163 Muenster, Germany**

SRN OF THE EC-REP:

DE-AR-000011194

START OF CE-MARKING:

2024-02-06

PLACE, DATE OF DECLARATION:

Shenzhen, 2024-02

LEGALLY BINDING SIGNATURE:

NAME: FENG GAO

**POSITION: PERSON RESPONSIBLE FOR REGULATORY CONFORMITY
(PRRC)**

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Annex specification:

P/N:100101; P/N:100102; P/N:100103; P/N:100104; P/N:100104A; P/N:1001048; P/N:100106; P/N:100110;
P/N:100111; P/N:100201; P/N:100202; P/N:100205; P/N:100301; P/N:100302; P/N:200101; P/N:200104B;
P/N:200105A; P/N:200105B; P/N:200107; P/N:200201; P/N:200204; P/N:200301; P/N:300101; P/N:300102;
P/N:300105; P/N:300105A; P/N:300105B; P/N:300106; P/N:300201; P/N:300202; P/N:300301; P/N:400101;
P/N:400102; P/N:400103; P/N:400104; P/N:400105; P/N:400106; P/N:400301A; P/N:4003018; P/N:400203;
P/N:400302; P/N:400303; P/N:400305; P/N:400306; P/N:400307; P/N:400308; P/N:400110; P/N:400111;
P/N: 500101; P/N: 500102; P/N:100204; P/N: 100107