

EC Declaration of Conformity



No. 2022032401

Name and address of the manufacturer:

Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang
District, Hangzhou City, 311121 Zhejiang, China.

SRN of the manufacturer:

CN-MF-000008465

Name and address of the European
Authorized Representative:

OBELIS S.A
Bd. Général Wahis, 53 1030 Brussels, Belgium.
Tel: +32 27325954, Fax: +32 27326003
E-mail: mail@obelis.net

SRN of the European Authorized
Representative:

BE-AR-000000106

Name and address of the Swiss
Authorized Representative:

OBELIS SWISS GmbH
Ruessenstrasse 12, 6340
Baar/ZG, Switzerland

We declare under our sole responsibility that
the medical device:

Sharps Containers

Intended use:

It is intended to be used for health-care purposes for safe
disposal of hazardous sharps such as hypodermic needles,
syringes, blood needles and so on.

Basci UDI-DI code:

697122740SCYA

UMDNS-code:

14423

UMDNS description (Device group):

Waste-Disposal Units, Sharps

Product type/specification:

alphacheck professional Sharp Container:
SC-0.2Y

of class:

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according to annex VIII of Regulation (EU)
2017/745 :

Rule 1

meets the provisions of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it. The
declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

Annex II+ Annex III, Annex IV.

Date of Doc validity:

2022-03-24

Hangzhou, 2022.03.24
Place and date

Zearou Yang / R18
Name and function (signature)
Zearou YANG /Regulatory Affairs Manager