ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 16 02 53112 017

Manufacturer:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do 24398
REPUBLIC OF KOREA

EC-Representative:

Obelis S.A.
Bd. Général Wahis 53
1030 Brussels
BELGIUM

Product Category(ies):

Products for determination of tumor markers (PSA) and In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: 74944565

Valid from: 2016-06-01
Valid until: 2019-11-02

Date, 2016-06-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 16 02 53112 017

Model(s):

- Products for determination of tumor markers (PSA)
  Model Name
  - Quantitative PSA Test, i-CHROMA PSA TEST®
  - AFIAS PSA
- In Vitro Diagnostic devices for self testing
  Model Name
  - i-CHROMA™ CRP
  - i-CHROMA™ HbA1c
  - i-CHROMA™ hCG
  - i-CHROMA™ iFOB
  - i-CHROMA™ Microalbumin
  - i-CHROMA™ PSA
  - i-CHROMA™ RF(IgM)/CRP
  - i-CHROMA™ Reader

Facility(ies):

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,
Gang-won-do 24398, REPUBLIC OF KOREA

Boditech Med Inc.
#3-2A, 56, Soyanggang-ro, Chuncheon-si, Gang-won-do 24232,
REPUBLIC OF KOREA