

The undersigned TAMARA BECKER, on behalf of MEDAGENT GMBH, delegated by the Manufacturer or by the Agent to register data pertaining to the medical devices stated below, on 23/03/2021 validates the following information:

System progressive:2084838

Trade name and model: MBA 10K-3M

Code assigned by the manufacturer (catalogue identifier): TMBA 15K-3M-B

Role of the user entering the DM: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE

Manufacturer: KERN & SOHN GMBH

CND Classification: BILANCE PESA NEONATI

Complete GMDN repertoire: A device used to obtain an infant's weight or monitor weight changes during critical care procedures. Mechanical infant scales typically consist of a weight tray and a beam lever system mounted on a hardened steel pivot point. Electronic infant scales usually consist of a weight tray, a flexure plate or bending beam, an electronic transducer, and an analog or digital display. Also called pediatric scales.

EC Classification: Classe I con funzioni di misura

Annex according to which the device was marked: Annex V Annex VII

Relation to other DMs: No

List of certificates

Certificate No.of the EC mark: 170746014

Certificate expiration date: 26/05/2024

Notified Body Code-Name: 0297 - DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGERMENTSYSTEMEN MBH

EC Directive 2003/32: No

Documentation Annex

Etichetta:TMBA_Typschild_geeicht (1).pdf

Istruzioni per l'uso:IFU MBA-M-BA-i-2119.pdf

Technical Data

Description: Baby scale

Presence of tissues /substances: No

Presence of medications: No

The main DM primary packaging materials need special disposal: No

Sterile: No

Disposable: No

Resterilisation methods list

Latex: during manufacturing, the product came in contact with latex molecules:

No

Latex: both the product and its primary package are latex free: Yes

DM materials in direct contact with the patient

Material: NESSUNO

System progressive:2084824

Trade name and model: MBA-A01

Code assigned by the manufacturer (catalogue identifier): TMBA-A01-A

Role of the user entering the DM: ALTRO SOGGETTO DELEGATO DAL

FABBRICANTE

Manufacturer: KERN & SOHN GMBH

CND Classification: DISPOSITIVI CON FUNZIONI DI MISURA - ALTRI

Complete GMDN repertoire: A device used to measure the height of a patient. It can be, e.g., a wall-mounted graduated scale or a free-standing vertical graduated rod with an adjustable cross-piece that is placed on the top of the patient's head. It may give analogue or digital readings.

EC Classification: Classe I con funzioni di misura

Annex according to which the device was marked: Annex V Annex VII

Relation to other DMs: No

List of certificates

Certificate No.of the EC mark: 170746014

Certificate expiration date: 26/05/2024

Notified Body Code-Name: 0297 - DEUTSCHE GESELLSCHAFT ZUR ZERTIFIZIERUNG VON MANAGEMENTSYSTEMEN MBH

EC Directive 2003/32: No

Commercial Data

Documentation Annex

Etichetta:TMBA-A01-A_Typenschild.pdf

Istruzioni per l'uso:IFU MBA-A01-BA-i-2012.pdf

Technical Data

Description: Mechanical height rod

Presence of tissues /substances: No

Presence of medications: No

The main DM primary packaging materials need special disposal: No

Sterile: No

Disposable: No

Resterilisation methods list

Latex: during manufacturing, the product came in contact with latex molecules:
No

Latex: both the product and its primary package are latex free: Yes

DM materials in direct contact with the patient

Material: ALLUMINIO

The undersigned states he/she is aware of the sanctions provided for in case of false statement (art.76 of the D.P.R. n. 445 dated 28.12.2000).