PRODUCT

VISUCORE® 500 by ZEISS

INSTRUCTIONS FOR USE

PRODUCER

CX ENGINEERING®

CX Engineering Sp. z o.o.
ul. Przemysłowa 17 | 32-083 Balice | POLAND

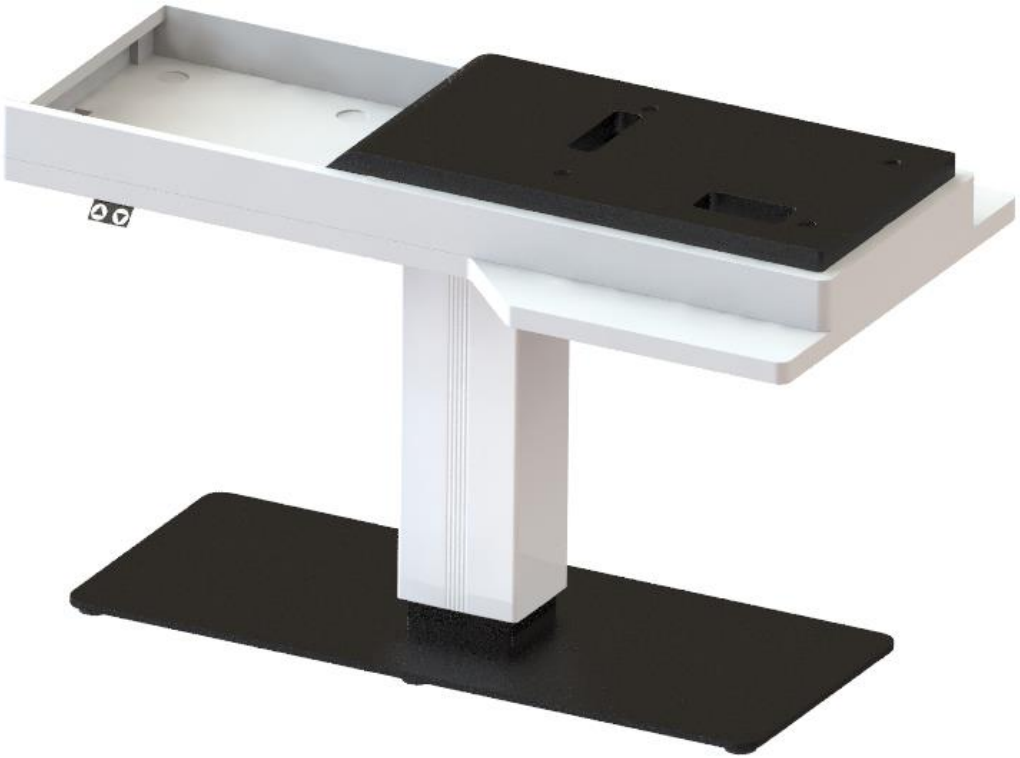
DISTRIBUTOR

ZEISS

Carl Zeiss Vision GmbH
Turnstrasse 27
73430 Aalen, GERMANY
www.zeiss.com

PRODUCT LABEL (EXAMPLE)

PARTS INCLUDED:



TECHNICAL SPECIFICATION TABLE	
Type:	VISU
Weight:	67 kg
Safe working load:	80 kg
Max. height:	934 mm
Min. height:	684 mm
Elevation speed:	12 mm/s
Supply:	100 - 240 V

OPERATING CONDITIONS	
Relative humidity:	10-90 %
Operating temperature:	+10°C - +40°C
Pressure:	500-1060 hPa

ACCOMPANYING DOCUMENTS
For full parts list and specification, please refer to the technical specification document

MADE IN EU

Rev 001, 01.08.2022, AJK

1 OPERATION

Activation
When supplied with electricity, the Table is active.
Visually inspect cables and electrical components for damage. Never use the product if you spot any damaged electrical components.

Height adjustment
Teburu XR ONE SC table is equipped in two hand switches and one foot switch to adjust the height of the table. Hand and foot set incorporates two buttons with triangular symbols corresponding to 'Up' and 'Down'. Press and hold button until the tabletop attains a desired height.
SAFETY PRECAUTIONS: Please avoid any hazards to the patient during the height adjustment.

Deactivation
When disconnected from the electricity, the Table is inactive.

Wheels locking
Teburu XR ONE table has a central locking system of wheels. You can lock all four wheels simultaneously with foot pedals located in both the cranial and caudal end of the table.

2 FAQ

Cleaning and maintenance
Use only soft cleaning agents and high quality cloth. To avoid bruising and smudging, polish the recently cleaned component with a soft, dry cloth. Please avoid soaking electricity components (cords, inlets etc.)

Disposal
Please see that Teburu fixation table contain parts that cannot be disposed in domestic waste. Please contact a waste management expert should you want to dispose of these.

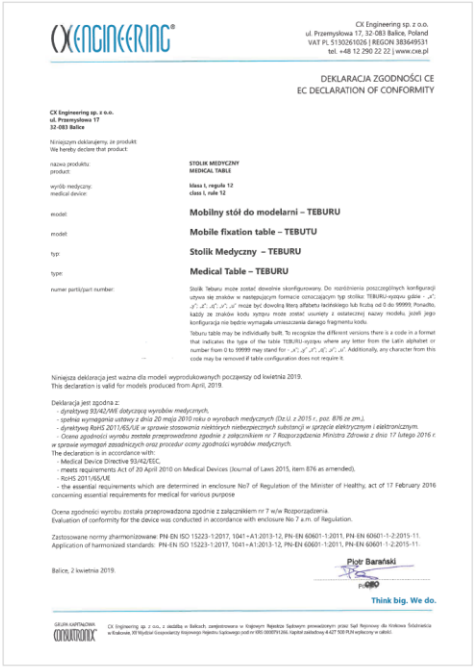
3 WARNING AND SAFETY NOTICES

Intended and Unintended applications
Teburu XR ONE SC is a mobile fixation table which gives excellent possibilities to index all different kinds of immobilization devices on top of it. Other aplications than specified may cause hazards and/or damage.

Liability of the Manufacturer
CX Engineering Sp. z o.o. considers itself responsible for issues on safety, reliability and performance only when:
- Any modifications and repairs are conducted by authorized persons AND.
- The product is used according to the manual.

Responsibility of the User
- Ensuring that electric supply is correct (see table on page 1).
- Cleaning and maintenance.
- Operation according to the manual.
- Storage in safe conditions.

DEKLARACJA ZGODNOŚCI



CX Engineering sp. z o.o.
ul. Przemysłowa 17, 32-083 Balice, Poland
VAT PL 5130261026 | REGON 383649531
tel. +48 12 290 22 22 | www.cxe.pl

DEKLARACJA ZGODNOŚCI CE
EC DECLARATION OF CONFORMITY

CX Engineering sp. z o.o.
ul. Przemysłowa 17
32-083 Balice

Niniejszym deklarujemy, że produkt:
We hereby declare that product:

nazwa produktu: product:	STOLIK MEDYCZNY MEDICAL TABLE
wyrób medyczny: medical device:	klasa I, reguła 12 class I, rule 12
model:	Mobilny stół do modelarni – TEBURU
model:	Mobile fixation table – TEBUTU
typ:	Stolik Medyczny – TEBURU
type:	Medical Table – TEBURU
numer partii/part number:	Stolik Teburu może zostać dowolnie skonfigurowany. Do rozróżnienia poszczególnych konfiguracji używa się znaków w następującym formacie oznaczającym typ stolika: TEBURU-«typ» gdzie - „x”, „y”, „z”, „a”, „b”, „c” może być dowolną literą alfabetu łacińskiego lub liczbą od 0 do 99999. Ponadto, każdy ze znaków kodu «typu» może zostać usunięty z ostatecznej nazwy modelu, jeżeli jego konfiguracja nie będzie wymagała umieszczania danego fragmentu kodu. Teburu table may be individually built. To recognize the different versions there is a code in a format that indicates the type of the table TEBURU-«type» where any letter from the Latin alphabet or number from 0 to 99999 may stand for - „x”, „y”, „z”, „a”, „b”, „c”. Additionally, any character from this code may be removed if table configuration does not require it.

Niniejsza deklaracja jest ważna dla modeli wyprodukowanych począwszy od kwietnia 2019.
This declaration is valid for models produced from April, 2019.

Deklaracja jest zgodna z:
- dyrektywą 93/42/WE dotyczącą wyrobów medycznych,
- spełnia wymagania ustawy z dnia 20 maja 2010 roku o wyrobach medycznych (Dz.U. z 2015 r. poz. 876 ze zm.),
- dyrektywą RoHS 2011/65/UE w sprawie stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym.
- Ocena zgodności wyrobu została przeprowadzona zgodnie z załącznikiem nr 7 Rozporządzenia Ministra Zdrowia z dnia 17 lutego 2016 r. w sprawie wymagań zasadniczych oraz procedur oceny zgodności wyrobów medycznych.

The declaration is in accordance with:
- Medical Device Directive 93/42/EEC,
- meets requirements Act of 20 April 2010 on Medical Devices (Journal of Laws 2015, item 876 as ermended).
- RoHS 2011/65/UE
- the essential requirements which are determined in enclosure No7 of Regulation of the Minister of Healthy, act of 17 February 2016 concerning essential requirements for medical for various purpose

Ocena zgodności wyrobu została przeprowadzona zgodnie z załącznikiem nr 7 w/w Rozporządzenia.
Evaluation of conformity for the device was conducted in accordance with enclosure No 7 a.m. of Regulation.

Zastosowane normy zharmonizowane: PN-EN ISO 15223-1:2017, 1041+A1:2013-12, PN-EN 60601-1:2011, PN-EN 60601-1-2:2015-11.
Application of harmonized standards: PN-EN ISO 15223-1:2017, 1041+A1:2013-12, PN-EN 60601-1:2011, PN-EN 60601-1-2:2015-11.

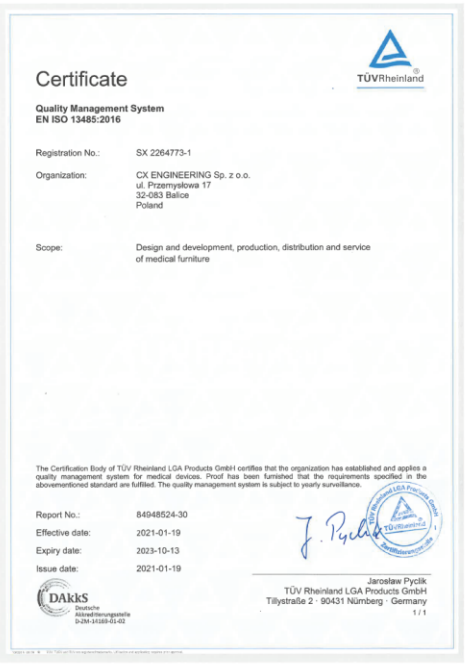
Balice, 2 kwietnia 2019.

Piotr Barański
Prezes

Think big. We do.

CX Engineering sp. z o.o., z siedzibą w Balicach, zarejestrowana w Sądzie Rejonowym dla Krakowa Śródmieścia w Krakowie, XI Wydział Gospodarczy Krajowego Rejestru Sądowego pod nr 0000391266, kapitał zakładowy 4 427 500 PLN wpłacony w całości.

CERTYFIKACJA ISO



Certificate

TÜVRheinland

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2264773-1
Organization:	CX ENGINEERING Sp. z o.o. ul. Przemysłowa 17 32-083 Balice Poland
Scope:	Design and development, production, distribution and service of medical furniture

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	84948524-30
Effective date:	2021-01-19
Expiry date:	2023-10-13
Issue date:	2021-01-19

DAkkS Deutsche Akkreditierungsstelle D-ZM-16188-01-02

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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4 EXPECTED POSITIONS

When using the table, Users are expected to be standing within safe distance when the height is adjusted. If no adjustment of the table setting is required, the wheels must be locked. Only then the users may use the tabletop to support their elbows or hand or palms.

5 EXPECTED POSITIONS

Please make sure that:
- the table is unplugged from electricity,
- no cords or plugs are hanging loose,
- the column is refracted to the shortest possible length,
- the equipment installed on the table does not exceed the contour of the table (e.g. edges of the table top, edges of the base plate),
- when pushing over thresholds the table is positioned sideways (i.e. longer edges of the tabletop are perpendicular to the obstacle),
- when pushing or dragging the table the force is not to be applied to the handset, cords, plugs,
- no body, clothing or equipment parts are to be positioned between the contour of the table and obstacles such as walls, door frames and other, when the distance between those shortens to values that may result in harm or hazard due to squeezing,
- feet are not to be run over by table wheels.