

TOWA MEDICAL INSTRUMENTS CO.,LTD.

Head office·factory: 1698-2 Nakano, Nakano-shi, Nagano, 383-0013, Japan
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Head office·factory

May 18, 2021

Declaration of Conformity

We declare, under our solo responsibility, that the products:

Product Name Trial Frame

Model No. TF-3

are in conformity with the EU Medical Devices Regulation (MDR), Regulation (EU) 2017/745

Classification Class I, Rule 1 according to Annex VIII of MDR

Basic UDI-DI 456220842TF0013H

This declaration of conformity is based on the Regulation (EU) 2017/745.:
2017/745 — concerning medical devices, Annex II

Manufacturer:

Name; TOWA MEDICAL INSTRUMENTS Co., Ltd.

Address; 1698-2 Nakano, Nakano-shi, Nagano, 383-0013, Japan

SRN; JP-MF-000004196

Authorized European Representative:

Name; Rexam Co., Ltd. Netherlands Office

Address; Steenovenweg 5, 5708HN Helmond, The Netherlands

SRN; NL-AR-000002643

The authorized signatory to this declaration:

Signature:

Name: Koichi Kasuya

Position: President

TOWA MEDICAL INSTRUMENTS CO.,LTD

Vertimas iš anglo kalbos



2021 m. gegužės 18 d.

Atitikties Deklaracija

Mes deklaruojame, su visa atsakomybe, kad produktai:

Produkto pavadinimas: Bandomieji rėmeliai

Modelio Nr.: TF – 3,
Atitinka ES Medicinos Priemonių Reglamento (MDR) (ES) 2017/745 reikalavimus

Klasifikacija Klasė 1, pagal MDR VIII priedo 1 Taisyklę

Bazinis UDI-DI 456220842TF0013H

Ši atitikties deklaracija parengta pagal (ES)2017/745 reikalavimus.: II Priedą.

Gamintojas: TOWA MEDICAL INSTRUMENTS Co., Ltd.
Adresas: 1698-2 Nakano, Nakano-shi, Nagano, 383-0013, Japonija
SRN: JP-MF-000004196

Autorizuotas atstovas Europoje:

Pavadinimas: Rexxam Co., Ltd. Olandijos atstovybė
Adresas: Via Solferino, 5 21057, Olgiate Olona, Italija.
SRN: NL-AR-000002643

Autorizuotas asmuo: /PARAŠAS/
Vardas: Koichi Kasuya
Pozicija: Prezidentas