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 DevicesRegulation (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; Rexxam 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