EC Declaration of Conformity

We hereby declare that the products of the product category

Product name and basic UDI-DI

MDF® 600 Professional-Grade Pocket illuminator 69402116600Q5
MDF® 611 Professional-Grade Pocket Luminix® II 69402116611QA
MDF® 621 Luminix® MDF® Professional Diagnostic Penlight 69402116621QD
MDF® 631 Professional-Grade Pocket Luminix® III 69402116631QG

Product Category (UMDNS-Code): **38-832** Light source, hand-held, battery powered

Manufactured by **MDF Instruments Medifriend Inc.**
3F Building 6 & 1F Building 2, 1898 Lai Yin Road
Jiu Ting Town, Song Jiang District,
201615 Shanghai, China

Applicable Standards: EN ISO 13485:2016, ISO2859-1:2019, ISO14971:2019, ISO 10993-10:2010; ISO 10993-5:2009; ISO 15223-1:2021; EN62366:2008

The intended purpose: The MDF penlight used as a personal light source that provides light for local examination.

Fulfils the General safety and performance requirements of Annex I of the MDR 2017/745 and are manufactured and placed on the market under the sole responsibility of the manufacturer following the regulation:

The products are classified according to **Annex VIII, rule I of MDR** as a medical device **class I**

Conformity Assessment Procedure: **MDR Annex IV**

No Notified Body is used in Conformity Assessment for the above products

Authorised Representative in EU: Medical Technology Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

Signed by Manufacturer:

Shanghai Oct.26.2022
Place, date

General Manager, Helen Wu