

# DECLARATION OF CONFORMITY



Annex IV - 745/2017 MDR

## BIEFFE ITALIA s.r.l.

As manufacturer of the products underneath listed, declare under its own responsibility that the products:

BFAL 43.43 OR - BFAL 43.70 OR - BFAL 43.70 OV  
BFAL 43.70 VE - BFAL 43.90 OR - BFAL 43.90 OV  
BFAL 43.90 VE - BFAL 43.120 OR - BFAL 43.120 OV  
BFAL 43.120 VE - BFAL 43.150 OR - BFAL 43.150 OV  
BFAL 43.150 VE - BFAL 86.120 OR - BFAL 86.150 OR

leading to the product family:

## STANDARD VIEWER

**BASIC UDI-DI: 805373671BFAL\_NEGWY**

**are in conformity**

with the essential requirements of the **745/2017 MDR** as Class I medical devices according to Annex VIII, Chapter III, Rule 1 (one).

*Carinaro, 13 May 2021*

BIEFFE ITALIA S.r.l.

Dr. Flavio Ferrazzano

CEO