COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment

DECLARATION OF CONFORMITY

The manufacture or his authorized representative established in the Community:

JDM srl

Via Alcide De Gasperi, 57 62010 Montecassiano (MC) Tel. 0733493170 Fax 0733494224

Declares that the new PPE described hereafter:

Model: READER

Type: REC39EY10 - REC39EY15 - REC39EY20 -

REC39EY25 - REC39EY30

Is in conformity with the provisions of:

- 1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- 2. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

UDI-DI: 805177367 REC39EY10 5P - 805177367 REC39EY15 5Z - 805177367 REC39EY20 5S - 805177367 REC39EY25 64 - 805177367 REC39EY30 5V

Additional information: Class I Medical Device

3. regulation (EU) 2016/425 and, where such is the case, whit the harmonized standard EN166:2001, And is identical to the PPE which is the subject of EC certificate of conformity no.: 10066 rev.04 submitted on 11/12/2020, as iussed by:

CERTOTTICA – Istituto Italiano per la Certificazione dei Prodotti Ottici Scrl

Supplementary Information: category II (Intermediate risk) PPE

Done at: Montecassiano, Italy

Date: 11/12/2020 General manager
(Alonso Saenz Dario Josè)