

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: TRACER
Type: T00IC – T10IC – T15IC – T20IC -T25IC – T30IC

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 T00IC 8R - 805177367 T10IC 8Y - 805177367 T15IC 9R - 805177367 T20IC 9T - 805177367 T25IC 9Y - 805177367 T30IC 9E

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.: 21001 Rev. 1 submitted on 08/11/2023, as iussed by:

CERTOTTICA – Istituto Italiano per la Certificazione dei Prodotti Ottici Srl

Supplementary Information: category II (Intermediate risk) PPE

Done at : **Montecassiano, Italy**

Date: 08/11/2023

General manager
(Alonso Saenz Dario José)

