

DECLARATION OF CONFORMITY



The manufacturer OMNIDERMAL BIOMEDICS S.R.L. declares under its own responsibility that the device reported below and the relative software necessary for its operation

Model or nr. Article	Denomination
WV01	WOUNDVIEWER

Satisfies all applicable dispositions of Directive 93/42/EEC, and subsequent amendments, on Medical Devices.

To such purpose, guarantees and declares, pertaining to the above-named device, the following that it satisfies the essential requirements requested by Annex I of the Directive 93/42/EEC.

Moreover OMNIDERMAL BIOMEDICS S.R.L. is committed to:

keep the technical documentation specified at point 3 of Annex VII of Directive 93/42/EEC at the disposal of the national authorities, for inspection purposes, for a period of five years from the date of manufacture of the product. The aforesaid documentation supports this declaration of conformity.

maintain an appropriate system for the monitoring of the device, in the phase successive to that of production, and to apply eventual necessary corrective measures, as prescribed in Annex VII of Directive 93/42/EEC.

It is therefore declared that the above-named device is in conformity with as much as prescribed by Directive 93/42/EEC and that it will be put on the market with CE mark, according to the dispositions of Article 17 of Directive 93/42/EEC.

Date: 25th February 2020

Place: Rubbiano di Solignano (PR), Italy

Signature of Legal Representative

