MILESTONE SCIENTIFIC®

EC DECLARATION OF CONFORMITY

Application of Council Directive:	93/42/EEC, Annex II.3 2011/65/UE
Name of Manufacturer:	Milestone Scientific, Inc.
Address of Manufacturer:	425 Eagle Rock Avenue Roseland, NJ 07068 USA
Name of Manufacture's Authorized Representative:	Medical Device Support Ltd. 3rd Floor, City Quarter, Lapps Quay, Cork, Ireland +353 21 424 4113
Type of Equipment:	System: CompuFlo Epidural Computer Controlled Anesthesia System - [Class IIb per rule 11] CompuFlo Epidural Disposable Kit - [Class IIa per rule 2]

Model Numbers:

CompuFlo™ Epidural Drive Instrument	EPI-6000-110, EPI-6000-220
CompuFlo™ Epidural Disposable Kit	EPI-6010
CathCheck Disposable Kit EPI	EPI-6010-5
CathCheck Disposable Kit (pre-assembled)	EPI-6010-03
CathCheck Disposable Kit box of 10 units	EPI-6100-03
CathCheck Disposable Kit box of 10 units non-assembled	EPI-6100-5
Epidural Disposable Kit (pre-assembled)	EPI-6010-01
Epidural Disposable box of 10 units	EPI-6100-01

Notified Body:

GMED SAS
1 rue Gaston Boissier, 75015 PARIS, FRANCE
CE 0459
Certificate No. 28071 rev. 4
Adendum No. 38606 rev. 1
NF EN ISO 13485:2016 – ISO 13485:2016
Certificate No. 36181 rev. 2

This declaration of conformity is issued under the sole responsibility of the manufacturer. I declare on behalf of Milestone Scientific that the devices mentioned above complies with all applicable essential requirements and applicable provisions of the Directives as listed above. I also declare that these devices do not contain or are manufactured with any animal products or by products.

This Declaration is valid for one year from the date of signature and covers the following: The CompuFlo Epidural Drive Instruments with serial numbers beginning with P14 and higher. For the Handpieces and Single use kits they should not exceeded their expiration date.

Place: Roseland, NJ 07068 USA

By: _____ Date: 16-Dec-2022

Timothy Huntington

Title: Senior Director of QA/RA

Revision Level	ECO #	Date	Description of Revision	Approvals
A	15-0009	3/23/15	Initial Release	S. Solomon
B	15-0030	6/17/15	Add RoHS2	S. Solomon
C	16-0026	9/19/16	For both IA and EPI Disposable Kits changed " Class IIa per rule 5&6" to "Class IIa per rule 2"	A. Patel
D	20-0004	1/23/20	Update Milestone and MDS address. Update certificate number.	S. Solomon I. Ali
E	21-0003	1/29/21	Update NB Certificate revisions	J. Maniscalco
F	21-0024	6/28/21	Update new Senior Director QA/RA Update list of model numbers to include additional products.	T. Huntington I. Ali
G	ECO-000032	8/12/22	Removed Intra-Articular and disposables from form. Updated revision of certificate no. 28071	T. Huntington I. Ali
H	ECO-000043	9/29/22	Updated revision of EC certificate, address of notified body, and add correct reference numbers.	T. Huntington I. Ali
I	ECO-000047	10/14/22	Update references to align with current EC Certificate	T. Huntington I. Ali
J	ECO-000053	12/14/22	Update to include added model numbers and to update certificate revision.	T. Huntington I. Ali