



INCAS
Medical Safety
Innovation

EU Declaration of Conformity

IN.CAS. S.r.l., in its capacity as the Manufacturer and sole party responsible for the medical devices placed on the market under its own name, hereby declares, under its sole responsibility, that the medical devices to which this declaration refers are in conformity with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745 on Medical Devices, and that the conformity assessment process referred to in Annex XI Part A of Regulation (EU) 2017/745 on Medical Devices has been followed by the Notified Body IMQ S.p.A. (NB 0051), which approved the CE marking with Certificate No. 206/MDR dated 26.03.2025.

Type of Device: "Systems for the disinfection of non-surgical aspirators"

Model (#)	Trade Name	Brand	Description
CMDS	. / .	IN.CAS.	Single-dose capsules/bottles for IN.CAS. non-surgical aspirators
KCM-SHOW	. / .	IN.CAS.	Non-surgical aspirator disinfection system (IN.CAS. line) with accessories
KCM-SPRIZ	. / .	IN.CAS.	Non-surgical aspirator disinfection system (S.P.R.I.Z. line) with accessories

Intended Use: "For the disinfection of equipment belonging to the product line called "IN.CAS. non-surgical aspirators."

BASIC UDI-DI: 805044414 DISINFECTANTS PS

Classification: IIa – Rule 16 Annex VIII of Regulation (EU) 2017/745

Certification Body: IMQ S.p.A. (NB 0051)

Quality Management System in compliance with:

- UNI CEI EN ISO 13485:2021

Any modification made to the medical device without authorization from IN.CAS. S.r.l. invalidates this declaration.

It is hereby declared that the device in question is marketed in a non-sterile package.

It is also declared that the undersigned will keep the CE documentation available to the Competent Authorities and the Notified Body for a period of 10 years from the date of manufacture of the last device covered by this declaration.

This declaration is valid for five years from the date of issue.

Dossobuono di Villafranca

Date: 15.06.2026

Legal Representative
Dr. Gianni Casamicheli



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Code List

Code (REF)	UDI-DI	Description	Model (#)
CMDS01	8050444140024	Non-surgical aspirator disinfection system (IN.CAS. line) Single-dose capsule for IN.CAS. line	CMDS
CMDS02	8050444140031	Non-surgical aspirator disinfection system (S.HO.W. line) Single-dose bottle for S.HO.W. line	CMDS
KCM-SHOW01-S.O.	8050444140017	Non-surgical aspirator disinfection system (IN.CAS. line) with accessories (suction tube, filter, cleaning cloth)	KCM-SHOW
KCM-SHOW03-ORT.	8050444140086	Non-surgical aspirator disinfection system (IN.CAS. line) with accessories (suction tube, filter, Y-connector, cleaning cloth)	KCM-SHOW
KCM-SHOW05-DIAL.	8050444140093	Non-surgical aspirator disinfection system (IN.CAS. line) with accessories (suction tube, multi-aspiration connector, cleaning cloth)	KCM-SHOW
KCM-SHOW06-ORT.	8050444140284	Non-surgical aspirator disinfection system (IN.CAS. line) with accessories (suction tube, filter, Y-connector, anti-reflux valve, cleaning cloth)	KCM-SHOW
CMDS04	8050444140246	Non-surgical aspirator disinfection system (S.P.R.I.Z. line) Single-dose bottle for S.P.R.I.Z. line	CMDS
KCM-SPRIZ10	8050444140291	Non-surgical aspirator disinfection system (S.P.R.I.Z. line) with accessories (suction tube, filter, cleaning cloth)	KCM-SPRIZ