Noul Co., Ltd.
B-6F, 10F, 338, Gwanggyojungang-ro, Suji-gu,
Yongin-si, Gyeonggi-do, 16942, Republic of Korea
Tel : +82 31 308 6310
Fax : +82 31 893 6672

DECLARATION OF CONFORMITY

We, **Noul Co., Ltd.**, hereby declare that:

A) Legal Manufacturer

Legal Manufacturer	Noul Co., Ltd.
Country of Origin	Republic of Korea
Legal Manufacturer Address	B-6F, 10F, 338, Gwanggyojungang-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16942, Republic of Korea
Manufacturing Site	B-6F, 9F, 10F, 338, Gwanggyojungang-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16942, Republic of Korea

B) Particulars of Medical Devices

No.	Product Name	Model Name
1	miLab™ Platform	DMLA
2	miLab™ Cartridge CER	CCEA
3	miLab™ Cartridge BCM	CBCA
4	miLab™ Cartridge MAL	CMAA
5	SafeFix™	CSFA
6	SafeFix™ CER	CSCA

C) Quality Management System certificate ("QMS")

Conformity Assessment Body	3EC International
Certificate No.	M-0543/24
Issuance Date - Expiry Date	29 May 2024 - 21 May 2026
Applied Standard(s)	EN ISO 13485:2016

D) Standards Applied

No.	Standard	Description
1	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems–Requirements for regulatory purposes
2	ISO 14971: 2019 EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
3	IEC 61010-2-101:2018 EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
4	IEC 61010-1:2010/A1:2016 EN 61010-1:2010/A1:2019/AC:2019-04	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
5	IEC 61326-1:2020 EN IEC 61326-1:2021	Electromagnetic compatibility (EMC) Directive
6	IEC 61326-2-6:2020 EN IEC 61326-2-6:2021	Electrical equipment for measurement, control and laboratory use-EMC requirements -Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
7	IEC 61000-3-2:2018/A1:2020/A2:2024 EN IEC 61000-3-2:2019	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
8	IEC 61000-3-3:2013/A1:2017/A2:2021 EN 61000-3-3:2013	Electromagnetic compatibility (EMC)- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
9	IEC 62366-1:2015/A1:2020 EN 62366-1:2015/A1:2020	Medical devices. Application of usability engineering to medical devices.
10	ISO 15223-1:2021 EN ISO 15223-1:2021	Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements
11	ISO 18113-1:2022 EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements.
12	ISO 18113-2:2022 EN ISO 18113-2:2011	In vitro diagnostic medical Devices. Information supplied by the manufacturer

No.	Standard	Description
		(labelling). In vitro diagnostic reagents for professional use.
13	EN 55011:2016/A2:2021	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement.
14	ISO 14644-1:2015 EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1 : classification of air cleanliness by particle concentration
15	ISO 14644-2:2015 EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2 : monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
16	EN 17141:2020	Cleanrooms and associated controlled environments. Biocontamination control.

Chan-yang Lim
CEO
August 25, 2025

Người đại diện hợp pháp của cơ sở
GIÁM ĐỐC
M.S.D.N: 0316765196 C.T.T.N.H.H CÔNG TY TNHH ASIA ACTUAL VIETNAM THÀNH PHỐ HỒ CHÍ MINH
Võ Trung Việt

Digitally signed by CÔNG TY TNHH ASIA ACTUAL VIETNAM
Location: TP.HCM