A.M.I. ITALIA S.r.l.
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A.M.I. Italia's Declaration in regards to Regulation 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD), (Directive Certificates) and their validity per Article 120.2 of Regulation (EU) 2017/745 on Medical Devices as amended by Regulation (EU) 2023/607 of 20 March 2023 (MDR) and with respect to the devices' – including devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body – and their manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3c of the MDR:

Manufacturer name	A.M.I. ITALIA S.R.L.
Manufacturer address	Via G. Porzio Centro Direzionale Isola G2, 80143 Napoli (NA), Italy
Single Registration Number (SRN)	IT-MF-000016770

Notified body name	IMQ S.P.A.
Notified body number	No. 0051
Directive certificate number to which this confirmation is	No. 1104/MDD *(see attached file 1104_MDD_2019_02_22.pdf)*
Date of validity as indicated on the Directive certificate	Directive 93/42/EEC on Medical Devices (MDD)
End date of extended validity/ transition period	31/12/2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive certificate** (or see attached Schedule if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive certificate(s) – if applicable -** as listed above or in the attached schedule
  - Directive certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid 26 May 2021, was/were not withdrawn by 20 March 2023, and
  - *Choose applicable statement:*

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☒ did expire before 20 March 2023

☒ before its date of expiry, a formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, MDR for conformity assessment was made for the devices(s) listed in the attached schedule or its substitute and a signed written agreement was in place in accordance with Section 4.3, second subparagraph, of Annex VII
(see attached files: FP-02000_23-fg10_2023-04-06.pdf)

☐ a Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR,

☐ a Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure.

☐ did *not* expire before 20 March 2023

☐ Where certificates expire *after* 20 March 2023, a formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII MDR for conformity assessment has been made or will be made/submitted to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is or will be in place in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

☐ Where certificates expire *after* 20 March 2023 and before 26 May 2024, if the manufacturer does not lodge an application for conformity assessment by 26 May 2024, the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose applicable statement:

☐ A QMS in accordance with Article 10(9) MDR has been put in place

☐ A notified body has issued the attached certificate for the MDR-compliant QMS

☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health

➢ We acknowledge that requirements relating to **post-market surveillance, vigilance, registration of economic operators** and of devices in accordance with MDR apply for the device family/ies as listed in the attached schedule.

Signed for and on behalf of the manufacturer:

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A.M.I. ITALIA S.R.L.

Naples, __/__/____

Eng. Sergio Arbitrio, CEO

Schedule of Devices

Identification of the device (e.g., device name, family/group name device model or catalogue number)		**Number of the Directive certificate(s)**	**Validity date as indicated on the Directive certificate(s)**	**Notified Body name and number**	**Extended validity date or transition period**
Geo Saver P	SGP-B0994 SGP-B0995	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
GeoSaver D	SGD-B0992 SGD-B0993	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
GeoSaver	SGS-B0988 SGS-B0989 SGA-B0990 SGA-B0991	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
S1-SaverOne P	S1P-B0986 S1P-B0987	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
S1-Saver One D	S1D-B0984 S1D-B0985	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
S1-Saver One	S1B-B0980 S1B-B0981 S1S-B0978 S1S-B0979 S1A-B0982 S1A-B0983	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
Saver One P	SVP-B0006 SVP-B0007	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
Saver One D	SVD-B0004 SVD-B0005	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028
Saver One	SVO-B0918 SVO-B0919 SVO-B0001 SVO-B0002 SVO-B0847 SVO-B0848	1104/MDD	15/02/2023	IMQ no.0051	31/12/2028

Naples, 20.04.2023

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