MEMO

Memo to: To Whom It May Concern

From : DEKRA Certification B.V. – Quality Assurance Department

Subject: Recognition as Auditing Organization under the Medical Device Single Audit Program (MDSAP)

Dear Madam/Sir,

DEKRA Certification B.V. is a recognized Auditing Organization under the Medical Device Single Audit Program (MDSAP).

Every year DEKRA Certification B.V. is assessed on compliance to the requirements set in the IMDRF MDSAP WG documents N3 and N4. The last MDSAP audit took place from September 27 - 30, 2022. The audit went very well with the assessment team leaders indicating to have full confidence in the ability of DEKRA Certification B.V. to perform reliable audits.

The MDSAP program authority has a renewed MDSAP recognition letter in preparation and will issue it when available.

As soon as DEKRA Certification B.V. has received the renewed letter of recognition, it will be posted on the website.

Hoping to have informed you sufficiently on the MDSAP status of recognition from DEKRA Certification B.V.

Kind Regards, Mr. Allard van Goor QA/RA Department Head

DEKRA Certification B.V.

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