

D8.4 NEC – Requirement No. 5

31/12/2021



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DOCUMENT SUMMARY INFORMATION

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Status	<input type="checkbox"/> Draft	<input checked="" type="checkbox"/> Peer Reviewed	<input checked="" type="checkbox"/> Coordinator Accepted

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HISTORY OF CHANGES

Version	Date	Changes
0.1	30/11/2021	Table of contents
0.2	07/12/2021	Initial version
0.3	14/12/2021	Review by the internal reviewers and the Independent Ethics Advisor
0.4	21/12/2021	Second version (reviewers' comments addressed)
1.0	31/12/2021	Final version

PROJECT PARTNERS

Partner No.	Logo	Partner	Short name	Country
1		INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS	ICCS	Greece
2		TOTALFORSVARETS FORSKNING SINSTITUT	FOI	Sweden
3		LEONARDO – SOCIETA PER AZIONI	LDO	Italy
4		C4CONTROLS LTD [TERMINATED]	C4C [TERMINATED]	UK [TERMINATED]
5		INTRASOFT INTERNATIONAL SA	INTRA	Luxembourg
6		INOV INSTITUTO DE ENGENHARIA DE SISTEMAS E COMPUTADORES, INOVACAO	INOV	Portugal
7		EXUS SOFTWARE MONOPROSOPI ETAIRIA PERIORISMENIS EVTHINIS	EXUS	Greece
8		UNIVERSITAT POLITECNICA DE VALENCIA	UPV	Spain
9		ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
10		DEVERYWARE	DW	France
11		PARTICLE SUMMARY	PARTICLE	Portugal
12		TREE TECHNOLOGY SA	TREE	Spain
13		EUROPAISCHE GESELLSCHAFT FUR TRAUMA -UND AKUTCHIRURGIE - ESTES	ESTES	Austria
14		INTERNATIONAL MR MID ASSOCIATION	MR MID	Sweden
15		UNIVERSITA DEGLI STUDI DEL PIEMONTE ORIENTALE AMEDEO AVOGADRO	UPO	Italy
16		ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	APHP-SAMU	France
17		UNIVERSITA CATTOLICA DEL SACRO CUORE	UCSC	Italy

18		MINISTERO DELL' INTERNO	MININT	Italy
19		AZIENDA SANITARIA LOCALE N 2 SAVONESE	ASL2	Italy
20		MAGEN DAVID ADOM IN ISRAEL	MDA	Israel
21		CARR COMMUNICATIONS LIMITED	CCL	Ireland
22		ASSOCIAZIONE CITTADINANZATTIVA ONLUS	CA	Italy
23		INTERDISCIPLINARY CENTER (IDC) HERZLIYA	IDC	Israel
24		ASTRIAL GmbH	ASTRIAL	Germany

LIST OF ABBREVIATIONS

Abbreviation	Definition
COTS	Component Off The Shelf
EU	European Union
EU COMMISSION IMPLEMENTING DECISION 2021	EU COMMISSION IMPLEMENTING DECISION 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council
ECJ	European Court of Justice
GDPR	General Data Protection Regulation
SCCs	Standard Contractual Clauses
TTX	Table-top exercise
VPN	Virtual Private Network

Executive Summary

This deliverable addresses the following requirements:

- » Details on the materials which will be imported to/exported from the EU
- » Copies of import/export authorisations, as required by national/EU legislation

Two categories will be imported to/exported from the EU (Israel): 1) data and 2) elements of the toolkit (the latter only temporarily in order to allow for a tabletop exercise to take place - TTX2, month 17 of the project).

Data will be imported to/exported from the EU, including 'sensitive data' as defined by applicable EU regulations, namely Article 4(13), (14) and (15) and Article 9 and Recitals (51) to (56) of the GDPR and relevant implementation decisions. 'Sensitive data' is subject to specific processing conditions that must be protected by equivalent conditions upon export/import between the EU and a third country (Israel in the case of the Nightingale project).

In principle, the authors of this deliverable have identified a three-step process in terms of applicable obligations related to import/export of data in and out of the EU, as follows:

- » **Step 1:** the existence of an **EU adequacy decision**: requires no further action from partners but to ensure the adequacy decision is valid with the designated State (Israel) at the time of export/import, alongside the usual obligations applicable for the collection, processing, storing, and sharing data, and especially 'sensitive data' such as health data, under the GDPR and all applicable domestic laws.
- » **Step 2:** in the absence or invalidity of an adequacy decision, the partners will apply **Standard Contractual Clauses (SCCs)** to any import/export of data between EU and a third country, as articulated by the latest EU Commission Implementation Decision of June 2021 (see below). This includes special consideration of 'sensitive data' under Annex I.B of that Decision.
- » **Step 3:** In the absence of an adequacy decision, and in case the national laws of the third country present specific challenges making the SCCs insufficient to protect data (including sensitive data), partners will apply **special protection measures** such as, anonymisation, pseudonymisation, restricting access to data to limited and defined personnel, security measures, etc.

Where elements of the toolkit to be temporarily exported to Israel in the framework of the tabletop exercise are concerned, D8.5 (DU – Requirement No. 6) on dual use risk assessment and mitigation measures and the requirement of export licences provides useful details. Further details are also to be found in the section of the present document “Materials which will be imported to/exported from the EU”.