Performed by:	Position:	Signature:	Date:
Liat Diamant Porat	CEO	Liat Diamant Porat	02/05/2022
Reviewed and approved by:	**Position:**	**Signature:**	**Date:**
Neta Landman	QA/RA Director and Team Leader	Neta Landman	02/06/2022

Impact assessment for new or revised regulation, directives, standards and guidance's		
New or revised standard/guidance name	**Old publication edition and date**	**New publication edition and date**
Medical devices — Application of risk management to medical devices	ISO 14971:2019	ISO 14971:2019/A11:2021

Section 1: ISO 14971:2019/A11:2021 Key changes

EN ISO 14971:2019+A11:2021, includes two informative Annexes that are an integral part of the 14971 standard. Annex ZA and ZB describe the relationship between the clauses of EN ISO 14971 and the General Safety and Performance Requirements (GSPR) of the MDR.

Section 2: New available definitions in ISO 14971:2019/A11:2021

NA, no new definitions were introduced in this amendment

Section 3: Updated definition in ISO 14971:2019/A11:2021

NA, no updated definitions were introduced in this amendment

Section 4: Comparison table

Comparison			
Clause in ISO 14971:2019	**Clause in 14971:2019/A11:2021**	**Comment on change**	**Required activities**
NA	Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	Annex ZA is applicable for devices regulated under MDR	Update GSPR checklist under technical documentation
NA	For application of this European standard under Regulation (EU) 2017/745, 1. the scope is limited to medical devices and accessories for a medical device as defined in that Regulation and to products regulated as a device under that Regulation; 2. in case of differences between terms defined in this European standard and terms defined in that Regulation, the terms defined in the Regulation shall prevail; 3. the manufacturer's policy for establishing criteria for risk acceptability (see 4.2 of this European standard) shall ensure that the criteria comply with the General Safety and Performance Requirements of that Regulation. Explanation on the correspondence of the standard and the General Safety and Performance Requirements is included in Table ZA.1.	-	-
NA	Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered	Annex ZB is applicable for devices regulated under IVDR	Update GSPR checklist under technical documentation
NA	For application of this European standard under Regulation (EU) 2017/746, 1. the scope is limited to in vitro diagnostic medical devices and accessories for in vitro diagnostic	-	-

Comparison			
Clause in ISO 14971:2019	**Clause in 14971:2019/A11:2021**	**Comment on change**	**Required activities**
	medical devices as defined in that Regulation and to products regulated as a device under that Regulation; 2. in case of differences between terms defined in this European standard and terms defined in that Regulation, the terms defined in the Regulation shall prevail; 3. the manufacturer's policy for establishing criteria for risk acceptability (see 4.2 of this European standard) shall ensure that the criteria comply with the General Safety and Performance Requirements of that Regulation.		