Registration No.: NAH-

AUDIT PLAN

ACCREDITATION CYCLE AUDIT PLAN

For bodies certifying according to Standard ISO 13485

Name of certification body:

Accreditation cycle:

Assessment criteria:
MSZ EN ISO/IEC 17021-1:2016, IAF MD1:2007, IAF MD2:2007, IAF MD3:2008, IAF MD4:2008, IAF MD 8:2015, IAF MD 9:2015IAF MD 10:2013, IAF MD 11:2013, EA 7/04:2007

IAF MD 9. Annex A	Critical areas Risk classification III	Accreditation procedure		1st year surveillance		2nd year surveillance		3rd year surveillance		4th year surveillance		Re-accreditation	
		HSZ	WA	HSZ	WA	HSZ	WA	HSZ	WA	HSZ	WA	HSZ	WA
A.1.1.	Contraceptive medical devices, Implants, Absorbable, drug-coated wound dressings, suture device												
A.1.2.	*Belonging not to critical areas risk classification III*												
A.1.3.	All technical areas												
A.1.4.	All technical areas												
A.1.5.	All technical areas												
A.1.6.	Medical devices incorporating medicinal												

	substances, Medical devices utilising tissues of animal origin Medical devices incorporating derivates of human blood Medical devices utilising biological active coatings												

HSZ: documents reviewed at site assessment
WA: witness audit
X: assessment of competence for complete code group