HS-360 Economy Four Wheel Mobility Scooter
Technical File -Master File

No.	Subject	Attendees & Responsibilities												content
		Document control	R&D Department	Production control	Quality Assurance	Production Technique	Procurement Division	Stamping Division	Production Division	Welding Division	Management Representative	Materials Division	Sales Division	
1	Device introduction													
1-1	Factory introduction										√			
1-2	Device description		√											(Researching proposal)
1-3	Device series		√											
	Specification		√											specification(annex I)
	Main/key materials		√											(annex I)
1-4	Intended purpose/users		√											
1-5	Classification		√											class I
2	GSPR													
2-1	Checking list		√											MDR 2017/745
2-2	List of applicable harmonized standards		√											MDR 2017/745
2-3	Test report		√											MDR 2017/745
2-4	Supporting evidence		√											MDR 2017/745
3	Product risk management(ISO14971)													
3-1	Flow chart		√											EN/ISO14971(attachment)
3-2	Q&A 2.1~2.34		√											EN/ISO14971(attachment)
3-3	D1~D8		√											EN/ISO14971(attachment)
3-4	Severity；Frequency		√											EN/ISO14971(attachment)
3-5	Tools for analysis		√											EN/ISO14971(attachment)
3-6	Information of Post-Market		√											EN/ISO14971(attachment)
3-7	Team of risk analysis, training and qualified		√											EN/ISO14971(attachment)
3-8	Product verification and validation		√											EN/ISO14971(attachment)
4	Design control													
4-1	Developing flow chart in accordance with ISO 13485, 7.3		√											(annex I)
4-2	Layout		√											LAY OUT(annex I)
4-3	Key/Safety parts；labeling				√									power moudle、charger(attachment) CE(annex I)
4-4	Carton；IFU…		√											attachment
4-5	Declaration of device conformity in accordance with harmonized stanard		√											(attachment RD10)
5	Product manufacturing procedure													
5-1	Flow chart in accordance with ISO13485, 7.5								√					GMP
5-2	Description of key manufacturing equipment								√	√				GMP
	Management /control for key manufacturing process								√	√				Welding and assembly (Assembly :CT-AS-M-0001_1.0_)

6	Device sterilization													
7	Biocompatibility													
8	Clinical evaluation													
9	Procedure for labeling control													
10	Declaration and conformity													
11	Preventive and Corrective Action													
12	Procedure for advising of design change													
13	Product catalogue													
13-1	Model name/ series													parts list(annex I)
13-2	Production technical data													product technical data (annex I)
14	CE TCF standard													
	Declaration and conformity in accordance with product harmonised standard													
	EN (http://www.europa.eu.int; newapproach.org)													EN60601-1-2
	ISO (http://www.iso.ch)													CISPR 14
	IEC (http://domino.iec.ch)													EN61326
	National standards													EN55011
15	CE TCF report													
15-1	Elecontronic products													
	EN60601-1(Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)													