



TEST REPORT IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	
Report Number..... :	64.66T.20.359.01
Date of issue..... :	2021-06-08
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Name of Testing Laboratory preparing the Report	TÜV SÜD Certification and Testing (China) Co., Ltd. – Guangzhou Branch 5/F, Communication Building, No.163, Pingyun Road, West of Huangpu Avenue, Guangzhou, Guangdong, China
Applicant's name	Hunan Beyond Medical Technology Co., Ltd.
Address..... :	Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha, Hunan, PEOPLE'S REPUBLIC OF CHINA
Test specification:	
Standard..... :	IEC 60601-1:2005, AMD1:2012
Test procedure	Voluntary Test
Non-standard test method	N/A
TRF template used	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. :	IEC60601_1S
Test Report Form(s) Originator :	UL(US)
Master TRF	2020-12-17
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Test item description..... :	High Flow Heated Respiratory Humidifier	
Trade Mark(s) :	HiFRes	
Manufacturer :	Hunan Beyond Medical Technology Co., Ltd. Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha, Hunan, PEOPLE'S REPUBLIC OF CHINA	
Model/Type reference :	HF8, HF7, HF6, HF8M	
Ratings :	100-240VAC, 50/60Hz, 2.5A Max. Class II, IP22, type BF applied part	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
☒	Testing Laboratory:	TÜV SÜD Certification and Testing (China) Co., Ltd. – Guangzhou Branch
Testing location/ address..... :		5/F, Communication Building, No.163, Pingyun Road, West of Huangpu Avenue, Guangzhou, Guangdong, China
Tested by (name, function, signature)..... :		Tony Li (Project Handler) 
Approved by (name, function, signature).... :		Ivan Ding (Project Reviewer) 
☐	Testing procedure: CTF Stage 1:	
Testing location/ address..... :		
Tested by (name, function, signature)..... :		
Approved by (name, function, signature).... :		
☐	Testing procedure: CTF Stage 2:	
Testing location/ address..... :		
Tested by (name + signature) :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature).... :		
☐	Testing procedure: CTF Stage 3:	
☐	Testing procedure: CTF Stage 4:	
Testing location/ address..... :		
Tested by (name, function, signature)..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature).... :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment): See photo documentations of 64.66T.20.359.01.	
Summary of testing:	
Tests performed (name of test and test clause): All applicable tests. The following clauses / collaterals were not part of the manufacturers order and therefore excluded from this testing: Clause 11.7 Biocompatibility, referencing ISO 10993 Clause 12.2/15.1 Usability, IEC 60601-1-6 Clause 14 PEMS Collateral IEC 60601-1-9 environmental safety Software - IEC 62304	Testing location: TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch 5F, Communication Building 163 Pingyun Rd, Huangpu Ave. West 510656 Guangzhou
Summary of compliance with National Differences (List of countries addressed): EU ☒ The product fulfils the requirements of EN 60601-1:2006/A1:2013/A12:2014. The text of the International Standard IEC 60601-1:2005+A1:2012 was approved by CENELEC as a European Standard without any modification.	
Statement concerning the uncertainty of the measurement systems used for the tests ☐ Internal procedure used for type testing through which traceability of the measuring uncertainty has been established: Procedure number, issue date and title: N/A ☒ Statement not required by the standard used for type testing	