

EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)



DoC nr: 2023-00499 (Ver.: 1)

We NEDIS, as manufacturer, declare that this Declaration of Conformity is issued under our sole responsibility
and belongs to the following products

of the brand: **Nedis**
and produced in: **China**

NEDIS article number	NEDIS article name
HCBL400WT	Blood Pressure Monitor

THE PRODUCTS MENTIONED IN THIS DECLARATION ARE IN CONFORMITY WITH:

Subject	Directive / Regulation	(Harmonised) Standard
Electromagnetic Compatibility Directive (EMC)	2014/30/EU	EN 60601-1-2:2015 + A1:2021
Medical Devices Directive (MDD)	(EU) 2017/745	EN 1060-1:1995 + A1:2002 + A2:2009 EN 1060-3:1997 + A1:2005 + A2:2009 EN 1060-4:2004 EN 60601-1-11:2015 EN 60601-1-6:2010 + A1:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A2:2014 EN 62304:2006 + AC:2008 + A1:2015 EN 62366:2008 + A1:2015 EN 980:2008 EN ISO 10993-1:2009 + AC:2010 EN ISO 10993-10:2013 EN ISO 10993-5:2009 EN ISO 13485:2016 + AC:2018 EN ISO 14971:2012 + EN ISO 15223-1:2016 EN ISO 15223-1:2012 + EN ISO 15223-1:2016 EN ISO 81060-1:2012 EN ISO 81060-2:2014 + EN ISO 81060-2:2019

RoHS	2011/65/EU + (EC) 2015/863	EN 50581:2012 EN 62321:2009 EN IEC 63000:2018
------	-------------------------------	---

SIGNED FOR AND ON BEHALF OF:

Place and date of issue: 's-Hertogenbosch, 2023-02-20
Name, function : Gard Moors, Compliance & Quality manager NEDIS
Company name : NEDIS

Signature:


De Tweeling 28 - 5215MC
P.O. Box 70509 - 5201CL
's-Hertogenbosch The Netherlands
+31 (0)73 - 599 1055
www.nedis.com