MedicCleanAir®

A Belgian - Swiss Cooperation

CE

Déclaration de Conformité / Declaration of Conformity / Konformitätserklärung / Verklaring Konformiteit

Wij **MedicCleanAir®**
Nous **Division of Walsberghe nv**
We **Melkmarkt 35**
Wir **B-2000 Antwerpen, Belgium**

Verklaren onder onze verantwoordelijkheid dat
Déclarons sous notre responsabilité que les produits
Declare under our responsibility that the products
Erklären in aller Verantwortung, dass das Produkt

MedicCleanAir® – PRO 100 + PRO 110
MedicCleanAir® – ISO 120 + ISO520
MedicCleanAir® – ISO 210
MedicCleanAir® – Remote Controls RC100/RC200
MedicCleanAir® – COMBI (see*)

Tot dewelke deze verklaring betrekking heeft, conform is aan de volgende standaardnormen en documenten
Auquel se réfère cette déclaration est conforme aux normes ou autres documents normatifs
To which this declaration relates is in conformity with the following standards or normative documents
Auf das sich diese Erklärung bezieht, mit den folgenden Normen oder normativen Dokumenten übereinstimmt

CB – TEST CERTIFICATE (°+*) (°) Electrosuisse ref. CH-7062-M2 06.10.2014+12-HG-0187.06+07 (safety) +.10 (EMC) +.11 (EMC)+.12 (EMC)+.13(EMC)
220-240V, 50-60Hz, 85W+175W
220V, 60Hz, 85W (*) SGS Tecnos SA - Barcelona Nr. 2116/0799 - examinations for Saudi Arabia
CLASS I, IPXO

Requirements	EN-Standards:
CISPR 11 (ed. 5); am1	EN 60335-1:2012
CISPR 14-1 (ed.5); am1; am2	EN 60335-2-65:2003 + A1:2008 + C1:2004 + A11:2004
CISPR 14-2 (ed.1); am1: am2	EN 55014-2:1997 + A1:2001 + A2:2008
*IEC 60335-1 (ed.5): 2010+*1:2010+*2:2011+*A1:2013	EN 50366:2003 + A1:2006
*IEC 60335-2-65 (ed.2): 2002; am1:2008 + C1:2004 (ed2)+*A2:2015	*EN 62233:2008
IEC 60601-1-2 (ed.3)	EN 61000-6-2:2005
IEC 61000-3-2 (ed.4); am1;am2	*EN 55014-1:2006 + A1:2009 + A2:2011
IEC 61000-3-3 (ed.3)	EN 61000-6-3:2007 + A1:2011
IEC 61000-6-2 (ed.2)	*EN 61000-3-2:2006 + A1:2009 + A2:2009
IEC 61000-6-2+3 (ed.2); am1	*EN 61000-3-3:2013
IEC 62233 (ed.1): 2005/2008 (EMF)	*EN 60335-2-40

GOST R 51317-3-2-99(IEC 61000-3-2-95)+GOST R 51317-3-3-99(IEC 61000-3-3-94)+GOST R 51318-14-2-99(CISPR14-2-97)
EN60601-1-2:07 + IEC 60601-1-2 (ed3): EMC requirements of class 1, medical electrical equipment according to foll. regulations: EC Directives / Commission Regulations: 93/42/EC – Medical Devices
Swiss Regulations: SR812/213 – Medizinprodukteverordenung (Ordinance concerning Medical Devices)

- For COMBI: EC Council Directives: 2006/42/EC + 2006/95/EC + 2004/108/EC

National Differences: EU Group Differences, EU Special National Conditions, EU A-Deviations,
CENELEC Countries + Affiliates (Belarus, Ukraine, Bosnia-Herzegovina, Servia, Albania, Georgia, Morocco, Tunesia, Egypt, Libya, Jordan, Israel) + Argentina, Australia, Brazil, Hong Kong, Iran, Korea, Mexico, New Zealand, Russia, Saudi Arabia, Thailand, United Arab Emirates, Vietnam – Azerbaijan, Chile.

Bij een verandering aan het toestel, dat eerst niet met ons wordt doorgesproken, verliest deze verklaring haar geldigheid. / Dans le cas que le dispositif soit adapté, cette déclaration perd sa valeur. / In case the product is changed in any way, this declaration loses its validity. / Bei einer Änderung des Produkts, die nicht mit uns abgestimmt und genehmigt wurde, verliert diese Erklärung ihre Gültigkeit.

Kamer van Koophandel Antwerpen-Waasland
Chamber of Commerce Antwerp-Waasland
11-08-2017
W. WEYTS

Antwerp-Belgium, 11th August 2017

Hendrik Van Passel
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Gedelegeerd Bestuurder

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