Digitally signed by Petuhova Iuliana
Date: 2019.11.28 17:42:14 EET
Reason: MoldSign Signature
Location: Moldova

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Orphée S.A.
19 Chemin du Champ des Filles
1228 Plan Les Ouates

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsabilité que
Dichiariamo sotto nostra responsabilità che
We declare under our sole responsibility that

das Medizinprodukt für die In-vitro-Diagnostik
le dispositif médical de diagnostic in vitro
il dispositivo medico-diagnostico in vitro
the in vitro diagnostic medical device

Cleaner for Mythic 22
Ref. HM22-001-1

mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG
avec la classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE
con la classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

☐ Produkt der Liste A, Anhang II / Dispositif de la liste A, annexe II / Dispositivo dell'elenco A, allegato II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II / Dispositivo dell'elenco B, allegato II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / Dispositif destiné à l'autodiagnostic non listé dans l'annexe II / Dispositivo per test autodiagnostico non elencato nell'allegato II / Device for self-testing not listed in Annex II
☒ Sonstiges Produkt / Autre dispositif / Altro dispostivo / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente

Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués

Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati

Applied common technical specifications, harmonised standards, national standards or other normative documents

EN 980:2008 Graphical symbols for use in the labelling of medical devices.

EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices.

EN 13640:2002 Stability testing of in vitro diagnostic reagents.

EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices.

EN ISO 18113-2:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use.

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Procedimentodi valutazionedellaconformità
Conformity assessment procedure

Annex III

Konformitätsbewertungsstelle (falls beigezogen)
Organe respons. de l'évaluat.de la conformité(si consulté)
Organo incaric. della valutaz. della conform. (se consultato)
Notified Body (if consulted)

N/A

Ort, Datum / Lieu, date /
Luogo, data / Place, date

Geneva 17 January 2017

Name und Funktion / Nom et fonction /Nome e funzione / Name and function

Janusz Płocica
President of the Board of Directors

Wojciech Suchowski
Member of the Board of Directors