



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

Mythic 22
Mythic 22 AL
Mythic 18
Only One (Ref. HM22-002-1)
Mythic 18-22 FLUSH-CLEANER
(Ref. HM18-011-025)
Cleaner for Mythic 22 (Ref. HM22-001-1)
Diluent for Mythic 22 (Ref. HM22-003-10)
Mythic 18 Cyanide free Lytic solution
(Ref. HM18-008-05 ; Ref. HM18-008-1)
Mythic 18 Diluent
(Ref. HM18-009-10 ; Ref. HM18-009-20)
Mythic 18-22 Enzymatic Cleaning Solution
(Ref. HM18-007-1)
MYT-3D (Ref. MYT306N)
MYT-3D (Ref. MYT302)
MYT-5D (Ref. MYT506N)
MYT-5D (Ref. MYT502)
MYT-CAL (Ref. MYTCAL2)

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 dispositivo / 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

N/A

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

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

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Procedimenti di valutazione della conformità
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)

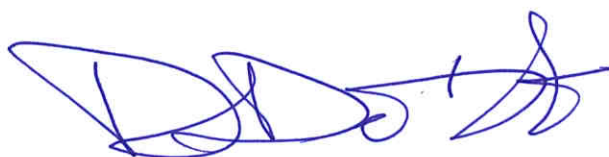
N/A

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

Geneva 9 November 2018

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

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Chief Sales Officer
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