



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 18 Cyanide free Lytic solution
Ref. HM18-008-05
Ref. HM18-008-1

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 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

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

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)

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

Geneva 15 March 2017

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

EN ISO 15223-1:2012 Medical Devices– Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

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.

Annex III

N/A

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